Issue 2: What Other Changes Were Made in This Section Between the Proposed and Final Rule?

Response. In paragraph (b), the term ''breast feeding infant'' was replaced with the term ''nursing infant.'' This was done to maintain consistency within Part 35. Paragraph (d) was revised to state that records of the instructions provided to breast-feeding females should be made in accordance with § 35.2075(b) rather and § 35.2075(c). This change was needed because of a change in the codified text of § 35.2075. For additional information refer to the discussion of § 35.2075.

Section 35.80, Provision of Mobile Medical Service

Issue 1: Should Mobile Medical Service Licensees Be Allowed To Operate Under Reciprocity in Other Regulatory Jurisdictions?

Comment. Commenters indicated that mobile medical services are currently operating under reciprocity in some States. Some Agreement States indicated they do not allow medical licensees to operate under reciprocity, while other Agreement States said they permit mobile medical services to come to their State under reciprocity.

Response. Agreement States have the flexibility of determining whether they will issue mobile medical licenses and whether they will allow NRC or other State licensees to operate in their State under reciprocity. Under reciprocity, an Agreement State may allow a specific licensee from another Agreement State (or the NRC) to work within the Agreement State without requiring the licensee to obtain a license in that State. Similarly, under reciprocity, a specific licensee from an Agreement State may work in NRC jurisdictions, provided the requirements in 10 CFR 150.20, Recognition of Agreement State Licensees, are met. Specifically, NRC allows Agreement State mobile medical service licensees to operate in areas under NRC jurisdiction provided they comply with all the requirements in § 150.20, including submittal of the information required in that section.

Issue 2: Should NRC Allow Byproduct Material To Be Delivered to a Client's Address of Use?

Comment. A commenter recommended that the NRC permit byproduct material to be delivered to the client's address.

Response. Byproduct material may only be transferred to an NRC or Agreement State licensee because the licensee is responsible for the safe handling of the material. In almost all cases, the client is neither an NRC nor an Agreement State licensee. Therefore, the material must only be transferred to the licensed mobile medical service. Byproduct material may be delivered to the mobile medical service licensee at the mobile site (i.e., mobile van) if the byproduct material is secured against unauthorized removal (§§ 20.1801 and 20.1802).

Issue 3: What Checks Should Be Performed on Instruments Used To Measure the Activity of Unsealed Byproduct Material at a Client's Address?

Comment. A commenter recommended that the check for instrument operation at the client's address be limited to a constancy check.

Response. Licensees must check the operation of instruments used to measure the activity of unsealed byproduct material to ensure that the instrument is functioning properly. This section was revised to require that licensees check instruments used to measure the activity of unsealed byproduct material for constancy before medical use at each client's address or on each day of use, whichever is more frequent. In the case of a mobile medical service, we believe that a constancy check must be performed to ensure that the instrument is functioning properly. The need for additional testing on the instruments is determined by how the licensee addresses compliance with § 35.60.

Issue 4: Is it Necessary To Check a Survey Instrument With a Dedicated Check Source?

Comment. A commenter recommended that the requirement to check the survey instrument with a dedicated check source be deleted because this check was no longer included in § 35.61.

Response. The NRC does not believe that the requirement to check survey instruments with a dedicated check source should be deleted from § 35.80. While we have deleted the requirement from § 35.61, we believe it is needed in § 35.80 because there is a greater likelihood that a survey instrument in a mobile unit may become damaged or uncalibrated as a result of extensive movement.

Issue 5: Do Mobile Medical Service Licensees Need To Collect Contaminated Waste Generated by Patients After Administration of the Byproduct Material?

Comment. A commenter asked that NRC clarify whether mobile medical service licensees need to return to the client's address to collect contaminated waste generated by patients after the administration of the byproduct material.

Response. The mobile medical service licensee does not need to return to the client's address to collect contaminated waste generated by the patient after the administration. The waste is no longer considered under the licensee's control because the patient would have been released from licensee control under § 35.75.

Issue 6: What Other Changes Were Made Between the Proposed and Final Rule?

Response. The NRC amended this section to use the term ''mobile medical service'' rather than ''mobile service'' to indicate clearly that the provisions in this section only apply to medical use. In addition, in paragraphs (a)(1) through (a)(4), ''client's address of use'' was replaced by ''client's address,'' which is defined in § 35.2. This was done to recognize that mobile medical service may be provided at an area of use or a temporary job site. (Area of use is defined as a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing byproduct material.)

Paragraph (a)(1) was also amended by replacing the term ''each entity'' with the phrase ''the licensee and the client.'' We believe this more clearly states our intent that the mobile medical service obtain a letter from each client that delineates the authority and responsibility of the licensee and the client.

Paragraph (a)(2) was amended to clarify that the instruments referred to in this paragraph refer to those instruments used to measure the activity of unsealed byproduct material.

In paragraph (b), ''the client's address of use'' was replaced by ''the client.'' This was done to clarify that byproduct material cannot be delivered to the client unless the client has a license allowing possession of the byproduct material.

Section 35.92, Decay-In-Storage

Issue 1: Should This Section Be Moved to Part 20?

Comment. Commenters believed that decay-in-storage should be addressed in Part 20 rather than in Part 35.

Response. Part 20 provides the general requirements for various waste disposal methods, including the decay-in-storage method. Currently, detailed procedures for decay-in-storage are in license conditions. The NRC believes the specific provisions for decay-in-storage that apply to a medical licensee should be codified in Part 35.

Issue 2: Should the Rule Continue To Require That Byproduct Material Be Held for 10 Half-Lives Before Disposal As Nonradioactive Material?

Comment. Commenters were divided in response to the NRC's request for specific comment on whether byproduct material should be held for a minimum of 10 half-lives. Commenters in favor of retaining the requirement believed that it would help ensure that the waste is not prematurely disposed of as nonradioactive material due to human error or instrumentation malfunction. They also believed that licensees may not have adequate survey instruments to survey low-energy beta emitters, such as sulfur-35 (S–35).

Commenters supporting the deletion of the requirement indicated that holding the byproduct material for 10 half-lives was in no way a guarantee that the waste could be disposed of as nonradioactive material. They believed that deletion of the requirement to hold the material for 10 half-lives would improve sanitary conditions and provide for more efficient use of storage space. Finally, they indicated that although S–35 is difficult to detect with a survey instrument, S–35 is not a component in any FDA-approved radiopharmaceutical for routine use.

Response. The NRC has not included a requirement in the final rule to hold byproduct material for 10 half-lives before disposing of the material as nonradioactive material. We do not believe this requirement is needed in light of the requirement in paragraph (a)(1) that precludes disposal of byproduct material without regard to its radioactivity until radiation levels adjacent to the material do not exceed background levels.

Issue 3: Does the Requirement To Obliterate Radiation Labels Only Apply to the Outermost Container, Especially if the Material Will Be Handled as Biohazardous Material?

Comment. A commenter questioned whether the obliteration of radiation labels is only required on the outermost container. Specifically, the commenter asked whether labels needed to be defaced on inner containers if the label on the outer container had been defaced and the inner label was not visible.

Response. NRC revised the text in paragraph (a)(2) to require that all radiation labels be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee. All radiation labels must be removed or obliterated from outer containers once the radioactivity can not be distinguished from the background level. Radiation labels on biomedical waste (e.g., sharps containers or individual needles and syringes) do not have to be removed or obliterated due to the associated biohazard of retrieving such material from the outer container. Also, in many cases, the waste barrels containing biomedical waste will be incinerated.

Issue 4: What Type of Byproduct Material May Be Held for Decay-In-Storage?

Comment. A commenter asked whether radioactive ''seeds'' can be held for decay-in storage.

Response. The final rule allows a licensee to hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity. If a ''seed'' contains byproduct material with a half-life of less than 120 days, this provision applies.

Issue 5: Were There Any Other Changes Made Between the Proposed and Final Rule?

Response. Yes. Paragraph (a) was revised to indicate clearly that the provisions in this section pertain only to disposal of the material without regard to its radioactivity. Licensees must continue to comply with any other regulations that pertain to disposal of the material (e.g., Environmental Protection Agency and State biomedical waste regulations).

Subpart D—Unsealed Byproduct Material—Written Directive Not Required

General Comments

Issue 1: What Are the Correct Titles for Subparts D and E?

Comments. Commenters recommended renaming Subparts D and E to avoid use of the terms ''low dose'' and ''high dose.'' A commenter recommended renaming these sections: Subpart D—Unsealed Byproduct Material—Written Directive Not Required and Subpart E—Unsealed Byproduct Material—Written Directive Required.

Response. The NRC agrees that the titles of Subparts D and E should be renamed to avoid use of the terms ''low dose'' and ''high dose.'' Subparts D and E in the final rule have been renamed to use the requirement for a ''written directive'' as the basis for associating the use of the material to radiation risk. The new titles are Subpart D—Unsealed Byproduct Material—Written Directive Not Required and Subpart E—Unsealed Byproduct Material—Written Directive Required.

Issue 2: Are the Regulations in Part 35 (except the training and experience requirements) Needed?

Comment. Commenters proposed removing the regulations for diagnostic nuclear medicine, except for the training and experience requirements, from Part 35. The commenters believed that properly trained physicians, with the assistance of other associated nuclear medicine health care providers and the standards of radiation protection in Part 20, are all that are necessary to protect the public health and safety adequately.

Response. During the development of the proposed rule, the NRC eliminated requirements in the current Part 35 that are contained elsewhere in the Commission's regulations, such as the radiation protection requirements in Part 20. Part 35 licensees will need to comply with these requirements, such as the ALARA provisions in Part 20, but we believe there is no need to duplicate requirements.

Part 20 contains general radiation protection requirements applicable to all licensees; Part 35 contains requirements specific to medical use licensees. While some commenters believe that Part 35 should not contain any requirements associated with low risk procedures, certain radiation protection-related requirements specific to medical use are needed in Part 35 because of their contribution to risk reduction. For example, the final rule retains requirements to perform quality control tests on instrumentation used to measure the radioactivity of patient dosages before administration. These regulations are necessary to provide high confidence that the instrumentation used to measure dosages is operating properly.

In other cases, more specific requirements were kept in Part 35 where justified by risk. The majority of those requirements deal with the therapeutic uses of sealed radioactive material. We believe that the requirements in the final rule are necessary, in addition to the requirements in Part 20, to ensure that the dosage administered to a patient is as prescribed by the AU and to ensure protection of workers and the public.

Issue 3: Should the Requirements for Diagnostic and Therapeutic Uses of Unsealed Byproduct Materials for Medical Use Be Combined?

Comment. A commenter believed that the proposed rule intermingled requirements for diagnostic and therapeutic nuclear medicine and failed

to provide a regulatory scheme appropriate to each.

Response. Early in the rulemaking process, the NRC considered structuring the rule to have completely ''stand-alone'' subparts for each type of medical use. However, under this approach, there would have been significant duplication of the requirements which would make the entire rule unnecessarily voluminous. For example, if we took this approach, each subpart would have had a section that addressed when a license was needed, criteria for amending a license, or RSO qualifications.

We have structured the rule so that Subparts A, B, C, L, M, and N contain the requirements that apply to all licensees. Subparts D, E, F, G, H, and K contain the requirements that apply to a particular modality, e.g., Subpart D provides specific requirements for the use of unsealed byproduct material which does not require a written directive, and Subpart E contains the requirements for the use of unsealed byproduct material which requires a written directive. The subparts for each type of use also contain the specific training and experience requirements for the AU.

Section 35.100, Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required

Issue 1: Why Doesn't the NRC Eliminate or Reduce the Regulation of Certain § 35.100 Materials?

Comment. A commenter recommended eliminating or reducing regulation of materials in § 35.100 with extremely low doses (e.g., 35 μCi of I–125 iothalamate, 10 μCi of iodine-125 (I–125) albumin and 1 μCi of cobalt-57 (Co-57) cyanocobalamin) because medical use of these materials involves minimal risk.

Response. The NRC does not believe that the requirements for the medical use of byproduct material described in § 35.100 should be eliminated. If this material is not handled safely, the public or occupationally exposed individuals could receive an exposure in excess of the Part 20 dose limits. However, we have reduced some regulatory requirements that apply to this type of use, e.g., the requirements in §§ 35.24, 35.61, 35.92, and 35.290 of the final rule. Explanations for these changes can be found in the discussions of the respective sections.

Issue 2: Should §§ 35.100 and 35.200 Be Combined Because the Procedures Performed in Both Modalities Do Not Require a Written Directive?

Comment. A commenter suggested that the two types of studies listed under Subpart D in the proposed rule in §§ 35.100 and 35.200 should be combined into one category, ''unsealed byproduct material for which a written directive is not required.''

Response. Early in the development of the proposed rule, the NRC considered combining these two categories into one section. We did not do so because we believe that the training and experience requirements for individuals using byproduct material for imaging and localization should be more rigorous than such requirements for individuals who only use unsealed byproduct material for uptake, dilution, and excretion studies. This is because AUs using unsealed material under § 35.200 are allowed to compound radiopharmaceuticals and, in general, are handling multiple types of radionuclides at higher activity levels than users performing uptake, dilution, and excretion studies.

Issue 3: Is the Reference in § 35.100(b) Referring to § 35.292 Correct?

Comment. A Commenter Suggested the Cross Reference in § 35.100(b) to § 35.292 Should Be § 35.290.

Response. The cross reference in § 35.100(b) of the proposed rule to an individual who meets the criteria to become an AU for use of unsealed byproduct material for imaging and localization is correct. The requirements in the proposed § 35.292 were moved to § 35.290 in the final rule, so § 35.100(b) now references § 35.290. The NRC also added a reference to § 35.390. Sections 35.292 and 35.390 in the final rule give physicians authorization to prepare radioactive drugs using generators and reagent kits. AUs qualified under the final § 35.190 (proposed § 35.290) do not have this type of authorization.

Issue 4: Why Aren't FDA-Approved IND Pharmacokinetic Studies Addressed in the Proposed Rule?

Comment. A commenter stated that the proposed rule did not recognize pharmaceutical companies that do not have a 10 CFR Part 35 license but label compounds with byproduct material and transfer them to specific licensees for use in FDA-approved IND pharmacokinetic studies. This commenter proposed addition of a new § 35.100(c) to address this issue.

Response: The final rule addresses this comment and other omissions in the proposed rule. The proposed rule did not recognize pharmaceutical companies who do not have a Part 32 license but who label compounds with byproduct materials and transfer them to a specific licensee for use in FDA-approved IND studies. The proposed rule also did not recognize the use of unsealed byproduct material obtained from an NRC or Agreement State licensee in accordance with an RDRC protocol. Finally, § 35.100 in the proposed rule did not allow specific medical use licensees, who do not have individuals qualified under §§ 35.292, 35.55, 35.920, or 35.980, to prepare unsealed byproduct material in accordance with an RDRC or IND protocol accepted by FDA for use in research. These omissions in the proposed rule unduly restricted labeling and transfer of unsealed byproduct material to Part 35 licensees. New paragraphs (c) and (d) have been added to §§ 35.100 and 35.200 of the final rule to address all of these situations.

Section 35.190, Training for Uptake, Dilution, and Excretion.

Issue 1: Is It Necessary for Physicians Using Byproduct Materials Under § 35.100 To Be Board Certified in Nuclear Medicine?

Comment. A commenter believed that there should be an alternative training and experience pathway for individuals who are not full board certified nuclear medicine physicians, but would like to become an AU for materials authorized under § 35.100.

Response. The final rule contains three pathways for individuals to become AUs for material under § 35.100. The first pathway, § 35.190(a), requires a physician to be certified by a board recognized by NRC. The second pathway, § 35.190(b), allows AUs, qualified under §§ 35.290, 35.390, or equivalent Agreement State requirements, to use byproduct material under § 35.100. The third pathway, § 35.190(c), requires that the physician complete 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The 60 hours includes classroom and laboratory training and work experience.

Issue 2: Were There Any Other Changes Made Between the Proposed and Final Rule?

Response: Yes. The training and experience requirements that were in the proposed § 35.290 were moved to § 35.190 in the final rule. This is

discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the **SUPPLEMENTARY INFORMATION.**

Section 35.200, Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required

Issue 1: Were There Any Changes Made in This Section Between The Proposed and Final Rule?

Response. Yes. Paragraphs (c) and (d) were added to this section in the final rule. These changes are identical to the changes made to § 35.100. The reasons for these additions are in the discussion of § 35.100, Issue 4.

Section 35.204, Permissible molybdenum-99 Concentration

Issue 1: Why Is It Necessary for NRC Regulations To Address molybdenum-99 (Mo-99) Concentrations?

Comments. Commenters argued for eliminating this section because U.S. Pharmacopeia (USP) and FDA standards already address this area. Another commenter believed that the proposed requirements were excessive and unnecessary. Some commenters supported the change in the requirement from evaluating the Mo-99 concentration for every elution, to evaluating it for only the first elution.

Response. The NRC believes that this requirement is necessary as a means to check generator eluate before medical use to ensure that the generator was not damaged in shipment. This requirement does not preclude more frequent evaluations of the Mo-99 concentrations. We revised paragraph (a) to express the permissible concentration level in SI units: ''0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).'' This level is identical to that used in the U.S. Pharmacopeia (USP) 23 U.S. Pharmacopeial Convention, Inc., 1995, pages 1486–1487.

Issue 2: Were There Any Changes Made in This Section Between the Proposed and final Rule?

Response. Yes. The NRC amended paragraph (c) to be more precise. We replaced the phrase ''measure molybdenum concentration'' with the phrase ''measure the molybdenum-99 concentration.''

Section 35.205, Control of Aerosols and Gases (current rule)

Issue 1: Should the Current Requirements Related to Aerosols and Gases Be Deleted?

Comment. The NRC received comments supporting and opposing the deletion of this section in the current rule. A commenter supported the deletion of the requirement because the current requirement is too prescriptive. Another commenter believed that the requirement to control radioactive aerosols and gases should be retained. This commenter stated that the requirement of having a negative pressure environment ensures that there is control over ''escaping radioactive gas.''

Response. The NRC does not believe this requirement is needed in Part 35. Part 35 licensees must comply with the occupational and public dose limits of Part 20. Additional prescriptive requirements for limiting airborne concentrations of radioactive material are not warranted in Part 35.

Section 35.290, Training for Imaging and Localization Studies

Issue 1: Should All Individuals Be Required To Have Experience With Eluting Generators?

Comment. A commenter recommended that the NRC revise the training and experience requirements in the proposed § 35.292 to state: ''To be authorized for possession and use of technetium from a generator system, the applicant must obtain supervised practical experience eluting technetium-99m from generator systems.'' The commenter is drawing a distinction between AUs that plan to limit their use to unit dosages, rather than preparing the dosages themselves. The commenter believed the requirement, as proposed, would be consistent with actual practice and good radiation safety practices. In addition, the commenter recommended that the preceptor not be required to certify that an individual has achieved a level of competency with regards to use of generators. Another commenter believed that we should delete requirements for individuals to receive training in eluting generators, measuring and testing the eluate for radiochemical purity and processing the eluate with reagent kits because unit dosages are obtained from a Part 32 licensee.

Response. The NRC has not modified the regulatory text to establish separate training and experience requirements for AUs only using unit dosages. We have also not deleted the requirement for ''eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.'' Physicians who meet all the qualifications in the final § 35.290 are authorized to use generator systems and reagent kits in the preparation of radioactive drugs and must be trained accordingly, even though they may elect to use only unit dosages. If a physician does not have experience in eluting generators he or she will be authorized for unit dosages only. For the same reason, we believe that the preceptor should certify that the individual has achieved a level of competency with regards to use of generators. We would unduly limit where a licensee may obtain unsealed byproduct material if we made any further revisions to the regulatory text.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response: Yes. The requirements in the proposed § 35.290 were moved to the final § 35.190. The requirements in the proposed § 35.292 were moved to the final § 35.290. This is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the **SUPPLEMENTARY INFORMATION.**

Subpart E—Unsealed Byproduct Material—Written Directive Required

Section 35.300, Use of Unsealed Byproduct Material for Which a Written Directive Is Required

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (b) was amended by changing the reference to § 35.292 in the proposed rule to § 35.290 in the final rule and adding a reference to § 35.390. The proposed rule would have allowed licensees to use any unsealed byproduct material prepared for medical use by an ANP, a physician who is an AU and who meets the requirements specified in the proposed § 35.292 (§ 35.290 of the final rule), or an individual under the supervision of either as specified in § 35.27. The NRC added the reference to § 35.390 in paragraph (b) of the final rule because a physician who meets the training requirements in § 35.390 also meets the training requirements in § 35.290.

Paragraphs (c) and (d) were added to this section. This was done because the proposed rule did not recognize pharmaceutical companies who do not

have a 10 CFR Part 32 license, but label compounds with byproduct materials and transfer them to a specific licensee for use in FDA-approved IND studies. Also, the proposed rule did not allow specific medical use licensees to prepare unsealed byproduct material in accordance with an IND protocol accepted by FDA for use in research. These omissions in the proposed rule unduly restricted labeling and transfer of unsealed byproduct material to Part 35 licensees. The final rule addresses these situations.

Sections 35.100 and 35.200 have been revised to address both the RDRC and IND approved material. Note: § 35.300, in contrast to §§ 35.100 and 35.200, does not include reference to RDRC authorizations because FDA's RDRC regulations restrict RDRC approvals to pharmacokinetic and physiological studies. Further, the dose limits for a study that can be approved by an RDRC under 21 CFR 361.1 are as follows:

(1) For a single administration of radioactive drug—whole body, gonads, blood forming organs, and lens—3 rem; all other organs—5 rem; and

(2) For multiple administrations (or annual dose commitment)—whole body, gonads, blood forming organs, and lens—5 rem; all other organs—15 rem.

Section 35.310, Safety Instruction

Issue 1: Who Must Participate in Annual Retraining on Radiation Safety?

Comments. Many commenters questioned the need for the radiation safety instruction required in § 35.310. Some commenters found this requirement to be very burdensome. A commenter suggested that posting radiation safety precautions on a patient's door or in the patient's chart could replace the training requirement. Another commenter believed that annual retraining was not needed for certified radiation therapy technologists and, therefore, recommended that the section specify annual retraining only for ''persons without specialized training in handling radioactive materials.'' Other commenters thought the requirement was too prescriptive, and that licensees should be given the freedom to decide how to assure compliance with the dose limits in § 35.75 on a case-by-case basis. According to another commenter, annual retraining should be required only for health care personnel who were not directly supervised by trained radiation safety staff. Some commenters argued against placing the radiation safety instruction requirement in Part 35, while other commenters suggested that we make the requirement only applicable to allied health workers who are not nurses. The commenter believed that the need for training should be dependent on whether the licensees needed to provide the individual with dosimetry. These commenters suggested that we revise § 35.310(a) to state: ''A licensee shall provide radiation safety instruction, initially and at least annually, to personnel, whose exposure rates may approach the limits in Part 20, caring for patient or human research subjects that have received therapy * * *''

Response. The NRC believes that it is important that personnel caring for patients or human research subjects, who cannot be released in accordance with § 35.75, receive instruction in limiting radiation exposure to the public and workers and in the radiation safety actions to be taken in the case of a medical emergency or death. We believe this provision is needed because exposure in excess of the public dose limits could result unless proper precautions are taken. We also believe this requirement is consistent with ALARA principles. We do not believe that only posting doors or a chart provides adequate information to the licensee's staff, without corresponding instruction.

The rule does not require the licensee to instruct all hospital staff. Instruction must only be provided to personnel caring for patients or human research subjects who cannot be released in accordance with § 35.75. We considered the comments regarding who should receive the training and whether the requirement should be linked to a dose limit. We decided that it is more appropriate to specify that instruction must be provided to personnel caring for patients or human research subjects, rather than tie the instruction to the dose limits in Part 20. This was done because it is possible for a licensee's staff member to receive a dose that is less than the occupational dose limits in Part 20, but take an action that could result in a dose to a member of the public that exceeds the public dose limit.

We have given the licensee flexibility on the level and detail of instruction that must be provided. The instruction need only be commensurate with the duties of the personnel. In other words, the licensee can determine the appropriate level of radiation safety instruction to be provided, depending on the level of care provided by the personnel. For example, a primary care nurse may receive detailed instructions on patient and visitor control, but the ward clerk may only need to be instructed to observe the caution signs on the patient's door.

We recognize that certified radiation therapy technologists or other individuals who have received specialized training in handling radioactive materials would have received training in the areas required by this section as part of a training program. However, we believe that refresher training is warranted because of the potential for unnecessary exposure to workers and the public if needed safety precautions are not observed.

Issue 2: Can the AU Have a Designee?

Comment: A commenter recommended that paragraph (a)(5) be revised to require that personnel be instructed to notify the RSO (or his or her designee) and the AU (or his or her designee) if the patient or the human research subject has a medical emergency or dies.

Response: The final rule provides the RSO flexibility in designating who should be notified to address radiation protection issues. However, the rule does not provide for the AU to have a designee. The AU is the individual who is responsible for the medical use and supervision of other persons using the byproduct material. Therefore, because of the type of dosages that are administered under § 35.300, we believe it is important that an AU be available to be contacted in case of a medical emergency or death.

Issue 3: Should the Current Requirements in § 35.315(a)(4) Related to Surveys Be Deleted?

Comment. A commenter indicated that removal of the current requirements in § 35.315(a)(4) to perform a radiation survey following a therapeutic administration of I–131 would be ill-advised. This commenter also believed that the requirement to perform a careful contamination room survey should not be removed.

Response. The NRC does not believe these survey requirements should be in Part 35. We believe Part 20 contains adequate information regarding radiation surveys. As required in § 20.1501, the licensee must make or cause to be made surveys that are needed to comply with the regulations in Part 20. Part 35 licensees are responsible for ensuring that the occupational and public dose limits in Part 20 are not exceeded.

Issue 4: Were There Any Other Changes Made to This Section Between the Proposed and Final Rule?

Response. Yes. In paragraph (a), the term ''radiopharmaceutical therapy'' was replaced with the phrase ''therapy with unsealed byproduct material.'' This change clarifies that this section addresses both drugs and biologics containing byproduct material. The term radiopharmaceutical does not cover both radioactive drugs and radiobiologics containing byproduct material.

Paragraph (b) of the proposed rule (paragraph (a)(5) of the final rule) was restructured to clarify our intent that, for the purpose of this section, only the RSO may have a designee.

Section 35.315, Safety Precautions

Issue 1: Does the Rule Allow the Licensee to Quarter Patients or Human Research Subjects Receiving Therapy With Unsealed Byproduct Material Together?

Comment. Commenters did not believe that the requirement to quarter a patient or human research subject, who cannot be released in accordance with § 35.75, in a private room with a private bathroom is justifiable. They believed that the requirement should be deleted, citing calculations suggesting that two patients undergoing identical radiation treatments (unsealed byproduct material) and occupying the same room would each have their total radiation dose increased by less than 1 percent due to the presence of the other patient. Others believed that allowing two patients undergoing treatment in the same room would be helpful as a means of controlling contamination and would, therefore, support ALARA principles.

Commenters also argued that allowing a nontherapy patient to share a room with a patient undergoing radiation therapy (unsealed byproduct material) was unacceptable. They said this would result in unnecessary exposure to a member of the public and would not be ALARA.

Other commenters opposed allowing the sharing of a posted restricted room with a patient who was not undergoing radiation therapy. These commenters were concerned about the radiation exposure to hospital housecleaning staff. Other commenters supported the requirement for a private room because they were concerned that medical institution management and health care insurance companies would not allow patients or human research subjects to be quartered in private rooms or in a double room (with single occupancy) because it was too expensive.

Response. The NRC revised this provision to allow the licensee to quarter a patient or human research subject in either (1) a private room with a private sanitary facility; or (2) a room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75. This requirement does not preclude the licensee from quartering the patient in a private room. This change recognizes that the exposure patients could receive from each other is insignificant in light of the exposure the patient is receiving from their administered dosages. Conversely, we do not believe that it is appropriate to allow a therapy and nontherapy patient to share a room because the nontherapy patient would not receive a radiation exposure under normal conditions.

We believe that contamination control is essential and that two patients could share the same room without negatively affecting the licensee's ability to control contamination. However, licensees should be mindful of the radiation hazards associated with different radionuclides, especially when quartering in the same room individuals who have received different radionuclides. We do not agree that sharing rooms will increase the exposure to housecleaning staff. Assuming that two patients require treatment, the exposure to the housekeeping staff should not be significantly different whether the patients are quartered in the same room or different rooms. In either situation, licensees have the responsibility to maintain the exposures below the Part 20 limits.

Issue 2: Should a Patient or Human Research Subject Be Allowed To Take Contaminated Articles Home?

Comment. A commenter asked that this section be revised to permit the licensee to package items contaminated with short-lived material so that the items could be released at the same time as the patient or human research subject. The commenter went on to state that the section should also include a requirement for the licensee to instruct the individual not to unpack the package and use anything in the package until a predetermined date. Finally, the commenter recommended that the date be calculated to ensure the activity remaining in the package is small.

Response. The NRC has not changed the rule because of the potential for unnecessary radiation exposure to the public if the material were not handled properly once it is released from licensee control. Any items contaminated as a result of medical use are the responsibility of the licensee.

Issue 3: Should Additional Requirements Be Added To § 35.315 To Address Hospitalization of Patients Who Can Be Released Under § 35.75, But Are Still Hospitalized Because of Medical Reasons?

Comment. A commenter questioned how a patient, who had been released under § 35.75, but was still hospitalized for another medical condition, should be managed. The commenter was concerned that the nursing staff could be confused by the instructions provided to the patient under § 35.75, because § 35.315 does not address the management of this type of patient. The commenter suggested that § 35.315 be revised to require licensees to implement radiation safety precautions, to include posting warning signs, whenever patients receiving therapy quantities of radiopharmaceuticals are hospitalized.

Response. It is the licensee's responsibility, under § 35.75, to control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is likely to exceed 5 mSv (0.5 rem).

We do not believe that § 35.315 should be revised to specifically address patients who are released in accordance with § 35.75 but remain hospitalized for other reasons because compliance with § 35.75 ensures that the maximally exposed individual does not receive a dose in excess of 5 mSv (0.5 rem).

Issue 4: Are the Limits in § 35.315 for the Release of Material and Items Removed From the Patient's or Human Research Subject's Room Appropriate?

Comment. A commenter was strongly in favor of the revised survey requirements because the previous rules were too prescriptive and not warranted for reasons of health and safety. Another commenter believed that the release limits in § 35.315(a)(3) of the proposed rule are unnecessarily low and are not logical when compared to the annual limit of intake for I–131 and I–125.

Response. Under § 35.315 (a)(4) in the final rule, material and items from the patient's or the human research subject's room cannot be removed until the radiation levels adjacent to the items are not distinguishable from natural background, unless the material and

items are managed as radioactive waste. Because this requirement is consistent with the release requirements in § 35.92 for radioactive waste, the NRC does not believe additional modification is needed.

Issue 5: Should the Bioassay Requirements in the Current § 35.325(a)(8) Be Included in the Final Rule?

Comment. A commenter asked that the current § 35.315(a)(8) be revised and incorporated in the final rule. The commenter recommended that the following provision be added: A licensee shall measure the thyroid burden of each individual who helped prepare or administer a dosage of I–131 within 3 days after administering the dosage if there is a likelihood that the individual would receive more than 10 percent of the Annual Limit of Intake in Appendix B of Part 20.

Response. The NRC has not included bioassay requirements in the final rule. Licensees are required to comply with Part 20. As such, they must limit occupational exposure to the limits in Part 20. In addition, they must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (§ 20.1101). This would include assessing whether individuals preparing or administering I–131 need bioassays.

Issue 6: Were There Any Other Changes Made to This Section Between the Proposed and Final Rule?

Response. Yes. The NRC restructured paragraph (b) to clarify our intent in the proposed rule that, for the purpose of this section, only the RSO may have a designee. This same change has been made in § 35.310. The reasons for this change are under the discussion of § 35.310, Issue 2.

Section 35.390, Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required

Issue 1: Should the Training and Experience Requirements in § 35.390 Include Instruction in Giving Radiation Safety Directions in the Event the Patient or Human Research Subject Dies?

Comment. A commenter recommended that the NRC add a requirement to § 35.390(b)(1) to require that an individual receive instruction on issuing radiation safety directions in the event the patient or human research subject dies.

Response. The NRC does not believe this change is necessary because this issue should be addressed as part of the licensee's overall radiation safety program. Licensees should have flexibility in how they address radiation safety issues associated with the death of a patient or human research subject.

Section 35.392, Training for the Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries)

Issue 1: Were There Any Changes Made in This Subpart Between the Proposed and Final Rule?

Response: Yes. The NRC added specific training and experience requirements for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi). This addition is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the **SUPPLEMENTARY INFORMATION.**

Section 35.394, Training for the Oral Administration of Sodium Iodide I–131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 millicuries)

Issue 1: Were There Any Changes Made in This Subpart Between the Proposed and Final Rule?

Response: Yes. The NRC added specific training and experience requirements for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 GBq (33 mCi). This addition is discussed in greater detail under the general discussion on training and experience located at the beginning of this section of the **SUPPLEMENTARY INFORMATION.**

Subpart F—Manual Brachytherapy

Section 35.400, Use of Sources for Manual Brachytherapy

Issue 1: Should All Therapy Sealed Sources Be Required To Have National Institute of Standards and Technology (NIST) Traceability?

Comment. Some commenters felt that all sources used for therapeutic applications should be required by regulation to have a NIST traceable national standard. Conversely, some commenters felt that it is inconsistent to require licensees to calibrate in the absence of national standards for all clinically used sources.

Response. This comment pertains to all sources used for manual brachytherapy under Section 35.400. Section 35.432 requires that source output be measured with a dosimetry system that has been calibrated using a system or source traceable to NIST. The NRC agrees with the AAPM position that all therapy sealed sources should be calibrated using a system or sources traceable to NIST and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by AAPM. In limited cases, a traceable standard identical to the therapy sealed source is not available. In these cases, the requirement allows the licensee the flexibility to use protocols accepted by nationally recognized bodies to meet the calibration requirement. As an example, AAPM Report No. 21—Specification of Brachytherapy Source Strength, 1987, recommends that sources used in radiation therapy have calibrations with direct or secondary traceability to national standards. AAPM defines direct traceability as ''when a source or calibrator has been calibrated either at NIST or an AAPM-Accredited Dosimetry Calibration Laboratory.'' AAPM defines secondary traceability as ''when the source is calibrated in comparison with a source of the same design and comparable strength which has direct traceability or when the source is calibrated using an instrument with direct traceability.'' In addition, AAPM TG–56 recommends that, for ''sources that do not have a national standard yet, users should develop a constancy check calibrated against the vendor's standard and use this constancy check to verify the source strength. Another option is to develop one's own secondary standard.'' This allows the licensee flexibility in the event that a direct NIST traceable standard does not exist.

Issue 2. Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added a new paragraph (b) to this section that allows a licensee to use therapy sources in medical research as long as the research is conducted in accordance with an active IDE application accepted by the FDA if the requirements in § 35.49(a) are met. This was done to clarify how research with sealed sources could be conducted if the medical use of the sources differed from the statements found in the SSDR for the sources. With this change, we allow the use of previously registered sources for uses other than those described in the original registration process, as long as the requirements in paragraph (b) are met.

Section 35.404, Surveys After Source Implant and Removal

Issue 1: Is the Requirement for Radiation Surveys After Brachytherapy Source Implant Necessary?

Comment. Commenters felt that a survey of the patient after brachytherapy sources have been implanted for the purpose of looking for misplaced sources would be difficult. The commenters stated that with the sources in the patient, the background around the patient is too high to detect an errant source. Additionally, some commenters believed that radiation surveys should be deleted from Part 35 because this is a Part 20 issue.

Response. The NRC agrees that Part 20 requires surveys and control of licensed material. However, in order to clarify that surveys must be conducted to locate and account for all sources that have not been implanted, the requirements for surveys have been retained in § 35.404(a). Section 20.1501 requires, in part, that each licensee shall make, or cause to be made, surveys that may be necessary for the licensee to comply with the regulations in this part and are reasonable to evaluate: the magnitude and extent of radiation levels; the concentration or quantities of radioactive material; and the potential radiological hazards that could be present. In addition, Subpart I of Part 20 requires that the licensee secure from unauthorized removal or control and maintain constant surveillance of licensed material. Because surveys under § 35.404(a) are not necessarily radiation surveys, the term ''radiation'' has been removed from the title and the text of paragraph (a) of this section. Depending on the area being surveyed and the ability to distinguish from the radiation background around the patient implanted with brachytherapy sources, these surveys may include radiation surveys of a facility room (e.g., operating room suite) after the patient with implanted sources has been removed from the room, radiation surveys in and around the patient's room after the implant, and visual surveys of the patient's bed after the implant.

Issue 2: Does Adjacent Area Include Contiguous Restricted and Unrestricted Areas?

Comment. A commenter requested that we explicitly indicate that ''adjacent area'' does not categorically include ''contiguous restricted and unrestricted areas.'' The commenter stated that the latter wording appears in the current § 35.415(a)(4). The commenter indicated there was little rationale for the current requirement and that it has been deservedly removed in the proposed rule.

Response. The NRC deleted the requirement in the current rule (§ 35.415(a)(4)) that required radiation surveys in contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of Part 20. We agree that this requirement is covered by Part 20. Deleting this requirement and relying on Part 20 to ensure that adequate surveys are performed provides the licensee flexibility in performing adequate surveys. For instance, an adequate survey following a brachytherapy implant may include a radiation survey of restricted and unrestricted areas with a maximally loaded patient in a representative patient room. If the circumstances of subsequent brachytherapy patient treatments are equivalent to the initial survey conditions, we believe that the licensee may rely upon the initial survey to show compliance with Part 20.

Section 35.406, Brachytherapy Source Accountability

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC changed the title of the section from ''Brachytherapy source inventory,'' to ''Brachytherapy source accountability.'' This title more accurately reflects the regulations in this section. The inventory requirements for sealed sources or brachytherapy sources are in § 35.67 of the final rule.

Section 35.410, Safety Instruction

Issue 1: Who Must Participate in Annual Retraining?

Comment. Many commenters questioned the need for the training required in § 35.410. Some commenters found this requirement to be very burdensome. Another commenter believed that annual retraining was not needed for certified radiation therapy technologists and, therefore, recommended that the section only require annual retraining for ''persons without specialized training in handling radioactive materials.'' Additionally, one commenter stated that initial and annual training of all nurses and all hospital staff was not cost effective.

Response. The NRC believes that it is important that personnel caring for patients or human research subjects, who have received a brachytherapy implant and cannot be released in accordance with § 35.75, receive instruction. This instruction should include information on how to minimize radiation exposures to the public and workers and the radiation safety actions to be taken in the case of a medical emergency or a death. We believe this provision is needed because exposures in excess of public dose limits could result if proper precautions are not taken. We also believe this requirement is consistent with ALARA principles.

We do not require training of all hospital staff. We allow the licensee flexibility in determining the appropriate level of radiation safety instruction to be provided, depending on the level of involvement by various personnel caring for the patient or human research subject. The instruction need only be commensurate with the duties of the personnel. For example, a primary care nurse may receive detailed instructions on patient and visitor control but the ward clerk may only need to be instructed to observe the caution signs on the patient's door.

We recognize that certified radiation therapy technologists, or other individuals who have received specialized training in handling radioactive materials, may have received training in the areas required by this section as part of their training program. However, we believe that refresher training is warranted because of the potential for unnecessary exposure to workers and the public if needed safety precautions are not observed.

Issue 2: When Notifying an AU Following a Patient Emergency, Can a Physician Designee Be Notified if the AU Is Not Available?

Comment. A commenter recommended that for notifications of patient or human research subject medical emergencies, the AU, like the RSO, may not always be readily available and should also have the option to specify a designee, such as another physician.

Response. Sections 35.11 and 35.27 permit an individual to use byproduct material under the supervision of an AU. Nevertheless, an AU, and not a designee, is responsible for the medical use and supervision of the byproduct material. In the event of a medical emergency involving a patient or human research subject implanted with brachytherapy source(s), the NRC believes that, because of the doses administered under § 35.400, an AU must be notified, and this notification cannot be delegated to a designee.

Issue 3. Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC restructured paragraph (a)(5) to clarify our intent that, for the purpose of this section, only the RSO may have a designee.

Section 35.415, Safety Precautions

Issue 1: Is It Necessary To List the Type and Location of Emergency Response Equipment in the Regulations?

Comment. Commenters believed that the requirement to list the contents of an emergency pack was too prescriptive and confusing. Additionally, commenters felt that the emergency equipment did not need to be specifically located in the patient's room but could be somewhere accessible in the hospital. Commenters felt that the licensee should have the freedom to adequately stock and locate an emergency pack. One commenter also felt that the phrase ''supplies necessary to surgically remove applicators'' kept in the patient's room implied that surgery should be conducted in a nonsterile environment.

Response. The NRC agrees with these comments because, in a performance-based rule, the essential objectives should be stated in the regulatory text. Therefore, we revised the regulatory text to identify the essential objective of having emergency response equipment available near each treatment room. The list of specific items that are needed for emergency responses has been deleted from this section. The licensee has the flexibility to determine the type of emergency response equipment needed to respond to a source that is either dislodged from the patient or lodged within the patient following removal of the source applicators.

We agree that the emergency equipment does not need to be maintained in the treatment room. However, it should be maintained near each treatment room in order to expeditiously respond to an emergency. The rule allows the licensee some flexibility in locating the emergency response equipment. The issue of whether to conduct surgical removals of applicators or sources within a treatment room that may not be a sterile environment is left to the licensee's discretion.

Issue 2: Can Brachytherapy Patients Be Quartered in the Same Room With a Patient Not Receiving Radiation Therapy?

Comment. The NRC solicited specific comment on the current requirement that the licensee not quarter a brachytherapy patient in the same room as an individual who is not receiving radiation therapy. The majority of commenters agreed with the requirement that would allow more than one brachytherapy patient in a room although a few commenters questioned this requirement. Some commenters believed that the final rule should retain the requirement that the licensee not quarter a patient in the same room as an individual who is not receiving radiation therapy. One commenter pointed out that a posted restricted room should not be shared with a patient not involved in the therapy. Another commenter believed that the requirement to prohibit placing a therapy patient in the same room as a nontherapy patient should apply not only to patients confined under § 35.75, but also to any patient where another individual in the room could receive over 1 mSv (0.1 rem). This commenter believed that limiting the requirement to only patients confined under § 35.75 was not ''as low as is reasonably achievable.'' Conversely, other commenters suggested that the provision for a private room be deleted.

Response. In the current Part 35, the NRC permits the sharing of a brachytherapy patient room with another ''individual undergoing radiation therapy.'' In the final rule, we clarified that the other ''individual undergoing radiation therapy'' refers to another brachytherapy patient. This is consistent with changes made to § 35.315 to allow therapy patients treated with unsealed material to share a room if they cannot be released under § 35.75.

We did not change the final rule in response to comments on the allowable exposure to the patient sharing the room or to individual members of the public. Section 20.1301 requires the licensee to conduct operations so that, in part, the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contributions, in part, from exposure to individuals administered radioactive material and released under § 35.75. Section 35.75 allows release of patients administered byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). Therefore, if the licensee confines a patient receiving brachytherapy and has not authorized the release of the patient under § 35.75, the licensee must limit the total effective dose equivalent to individual members of the public to less than 1m Sv (0.1 rem) in a year. Concurrent with this Part 35 rulemaking is a new provision in 10 CFR 20.1301(c) that allows a licensee to permit visitors to individuals who cannot be released under § 35.75 to receive a radiation dose not to exceed 5 mSv (0.5 rem), provided the authorized user has determined that it is appropriate. Alternatively, if the licensee authorizes the release of the patient receiving brachytherapy under § 35.75, the licensee must make the determination that the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem). The licensee must also provide the released individual, or the individual's parent or guardian, with instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable, if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). In all cases, the licensee is required, under § 20.1101, to conduct operations to achieve doses that are as low as is reasonably achievable.

Issue 3: Where Should ''Radioactive Materials'' Signs Be Posted?

Comment. A commenter suggested that having the option to put ''Radioactive Materials'' signs in the chart instead of on the door was not a good idea. This commenter felt that signs should be posted on the door and in the chart.

Response. Section 35.415(a) in the current rule specifically states that the patient's door has to be posted. The NRC revised this section to require that the licensee visibly post the patient's or human research subject's room with a ''Radioactive Materials'' sign. We also revised this section to allow the licensee flexibility in determining where to place the posting so that it is visible. Notations as to where and how long visitors may stay may be placed in the patient's chart or posted on the door.

Issue 4: Why Is There a Difference in the Time Periods To Notify the AU and the RSO, or his or her Designee, if the Patient or Human Research Subject Dies or has a Medical Emergency?

Comment. A commenter suggested that the time periods for notification of a medical emergency and death should be the same.

Response. The NRC agrees with the comment. In the final rule, the notification time periods are the same whether the patient or human research subject has a medical emergency or dies. We also modified this section to require that, in the event of a medical emergency, the notification should be as soon as possible, rather than immediately, because the licensee's

primary responsibility during a patient's medical emergency is the care of the patient.

Issue 5: Following a Patient Emergency, When Should an AU Versus an RSO Be Notified and Can A Physician Designee Be Notified if the AU is not Available?

Comment. A commenter felt that the AU should be notified and the notification of the RSO should be left to the AU's discretion. Another commenter recommended that for notifications of medical emergencies, the AU, like the RSO, may not always be readily available and should also have the option to specify a designee, such as another physician.

Response. Sections 35.11 and 35.27 permit an individual to use byproduct material under the supervision of an AU. Nevertheless, an AU, and not a designee, is responsible for the medical use and supervision of the byproduct material. Therefore, under § 35.415(c) an AU and not a designee, must be notified in the event that a patient or human research subject has a medical emergency or dies. Under § 35.24, the RSO is responsible for implementing the radiation protection program. Therefore, we believe that notification of the RSO, or his or her designee, provides additional assurance that appropriate corrective actions to respond to any radiation safety hazard associated with the emergency or death are taken.

Issue 6. Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (a) was reworded to make it clear that the requirements in § 35.75 apply to the release of individuals, not to the confinement of individuals. In addition, paragraph (c) was restructured to clarify our intent that, for the purpose of this section, only the RSO may have a designee.

Section 35.432, Calibration of Brachytherapy Sources

Issue 1: What Does the Term ''Nationally Recognized Body'' Mean and What Is the Policy for Taking Recommendations From These Bodies and Making Them Regulations?

Comment. Commenters questioned what was intended by the term ''nationally recognized body'' and stated that professional protocols may contain items that are recommended, but that were never intended to be adopted as regulations.

Response. Examples of nationally recognized bodies include ANSI, AAPM, ACR, ACMP, and NIST. Documents issued by nationally recognized bodies include multiple peer-reviews of the reports, protocols, or standards. The requirements in this subpart are based on recommendations found in AAPM TG–40 and TG–56 and are consistent with the calibration requirements for sealed sources and devices for therapy, including those found in ANSI documents. However, the NRC did not include all the recommendations made in these reports because we recognize the prescriptiveness of various reports. Instead, the regulation contains only the essential objectives for the test being required. For additional information on the use of consensus standards in developing the revision of Part 35 refer to Section I, Background.

Issue 2: What Is the Meaning of the Term ''Intervals Consistent With 1 Percent Physical Decay?''

Comment. One commenter requested that we clarify whether the requirement meant 1.0000 percent or allowed rounding down to 1 percent. Some commenters felt that 1 percent was too prescriptive because the calibration requirements are higher. Additionally, a commenter stated that correcting the output/activity at '''intervals consistent with 1 percent physical decay'' was not feasible for short half-life sources.

Response. This section requires that outputs or activities be corrected for physical decay at intervals consistent with 1 percent physical decay. ''Rounding'' is a mathematical term. ''Consistent with 1 percent'' includes from 0.51 percent to 1.49 percent. The 1 percent correction is separate from the calibration. The accuracy of the calibration must be within a given percentage provided by the published protocol used to perform the calibration. This calibration is then used to determine the dose delivered to the patient.

Issue 3: Should the Rule Contain a Requirement To Perform Calibration Measurements of Brachytherapy Sources and, if so, Can the Licensee Rely on the Manufacturer's or Distributor's Calibration?

Comment. In the proposed rule, the NRC solicited specific comment on requirements for brachytherapy source calibrations. Some commenters felt that the vendor's calibration should be verified by the licensee because use of unverified vendor calibrations poses serious hazards for the patient. Other commenters believed that the calibration of brachytherapy sources should be the manufacturer's responsibility. They also suggested that we could easily verify procedures at a few manufacturers, rather than at multiple hospitals. Some commenters also requested that we require the manufacturer to guarantee the source activity or output within 3 percent.

Response. The NRC believes that it is good practice to verify the calibration provided by the manufacturer because of the high risk associated with therapy doses to patients. Therefore, § 35.432 requires a licensee to perform calibration measurements before the first medical use of a brachytherapy source. The licensee shall determine the source output or activity using a dosimetry system that meets the requirements of § 35.630(a); determine source positioning accuracy within applicators; and use published protocols accepted by nationally recognized bodies to meet the previous two requirements.

However, we also believe that licensees should be able to use calibration measurements provided by the source manufacturer or by a calibration laboratory accredited by the AAPM as long as it was done in accordance with a published protocol accepted by a nationally recognized body using appropriately calibrated equipment. In order to ensure the reliability of the outputs or activities reported by the manufacturer, the manufacturer must perform the calibrations in accordance with the same requirements placed on the licensee. This also addresses the issue that the manufacturer guarantee the activity or output because the manufacturer must use at least the same performance standard as the licensee.

Issue 4: What is the Meaning of the Term ''Full'' in ''Full Calibration?'

Comment. A commenter suggested that the title be changed to ''Verification of calibration measurements of brachytherapy sources.'' Another commenter requested clarification of the term ''full'' in ''full calibration.'' Another commenter suggested that the term ''full calibration'' be replaced with ''spot check'' and the phrase ''spot check assay'' should be added to be consistent with terminology used in AAPM TG–40 and TG–56.

Response. The NRC agrees that the term ''full'' is confusing in the title because we do not define ''full.'' Therefore, the title of this section has been changed to ''Calibration measurements of brachytherapy sources.'' Also, the term ''full'' has been deleted from the regulatory text in this section. The terminology, including ''calibration,'' was selected to be consistent with terminology used in

Subpart H of Part 35 and in AAPM and ANSI reports.

Issue 5: When Should the Brachytherapy Sources Be Calibrated?

Comment. A commenter requested clarification on whether brachytherapy sources should be calibrated before the first medical use period or before the first medical use at a given facility.

Response. As written, the requirement is that each licensee must calibrate its brachytherapy sources before the first medical use at the licensee's facility. If the licensee is licensed for medical use at more than one facility in a single license, this calibration must only be performed once, before medical use, at any of the facilities listed in the license.

Issue 6: Does the Rule Allow Calibration of a Sampling of Sources When a Batch of Sources is Received?

Comment. Some commenters suggested that for short half-life sources and pure beta-emitting sources [e.g., I–125 and palladium–103 (Pd–103)], a sampling of the sources should be allowed.

Response. The NRC does not preclude a sampling of short half-life sources when received in a large batch. The rule requires that the calibration be performed using published protocols accepted by nationally recognized bodies, such as AAPM. The AAPM, in the report from TG–40, recommends for short half-life sources that ''for groupings with a large number of loose seeds, a random sample containing at least 10 percent of the seeds be calibrated'' and ''for a large number of seeds in ribbons, a minimum of 10 percent or 2 ribbons (whichever is larger) should be calibrated.'' However, this recommendation is made to the end user and as a verification of the source strength measurement performed by the manufacturer. The licensee must ensure that the published protocol allows for sampling of sources that have not been previously calibrated.

Issue 7: Are Sources Currently in the Possession of the Licensee Exempt From the Calibration Requirement?

Comment. A commenter suggested that we include an exemption for sources in inventory before the requirement becomes effective.

Response. Because calibration standards and methods have varied over the years, the NRC believes that to ensure that the correct dose is given to the patient, in accordance with § 35.41, the brachytherapy source output or activity must be calibrated in accordance with published protocols currently accepted by nationally recognized bodies. Therefore, we did not revise this section to include the requested exemption for sources in inventory before the effective date of the rule. Instead, we revised this section to clarify that all brachytherapy sources must be appropriately calibrated before the first medical use after the effective date of this rule. By including this date, the rule now clearly indicates that sources currently possessed by the licensee must be calibrated before the first medical use after the effective date of this rule and in accordance with a published protocol accepted by a nationally recognized body. If the source was previously calibrated in accordance with a currently accepted published protocol and using a dosimetry system that meets the requirements of § 35.630(a), the calibration would not need to be repeated after the final rule becomes effective.

Issue 8: Are the Calibration Requirements for High-Dose Versus Low-Dose Sources the Same?

Comment. A commenter requested that the calibration requirements make a distinction between high-dose and low-dose brachytherapy sources.

Response. The NRC does not believe that such a distinction is needed. We believe that when a therapeutic dose is delivered to a patient or human research subject, the licensee is responsible for ensuring that the correct dose is administered, regardless of the source strength.

Issue 9: Do the Manufacturer's Measurements Need To Be Performed Consistent With Those Required by the Licensee?

Comment. A commenter suggested that for the manufacturer's accepted measurements, the phrase ''that are made in accordance with the requirements of this section'' be deleted.

Response. This phrase has been retained in the final rule. To ensure the same level of calibration, the NRC believes that unverified calibrations performed by the manufacturer must meet the same calibration standard as the calibrations required of the licensee.

Issue 10: Is the Requirement for Source Positioning Accuracy Necessary?

Comment. Some commenters felt that the requirement for source positioning accuracy within applicators was vague and may be irrelevant or impossible to comply with.

Response. The NRC believes that, in order for the licensee to ensure further that the correct dose is delivered, the applicators used to help deliver the dose must be appropriately tested. We reviewed several standards currently available for calibration of brachytherapy sources. For example, AAPM TG–40 recommends, at a minimum, that initial tests be performed on brachytherapy applicators. TG–40 states that ''of major concern is that the applicators position the source where they are intended to be localized, and that any part of the structures which are used to attenuate the radiation (e.g., rectal and bladder shields) have not shifted.''

Issue 11: Should the Accuracy of Source Activity or Output Determination Be Stated in the Rule?

Comment. A commenter suggested that the accuracy for I–125 be changed to 10 percent because a 5 percent accuracy is not possible.

Response. The NRC deleted the reference to +/-5 percent from § 35.432(c)(1) of the proposed rule. We do not believe that the accuracy of the source activity or output measurement needs to be stated in the rule because the published protocol addresses the accuracy requirement.

Issue 12: Is New Equipment Required by Licensees To Perform Calibrations?

Comment. Several commenters indicated that the new requirement to calibrate brachytherapy sources would require licensees not currently involved in teletherapy or remote afterloader therapy to procure equipment. Additionally, a commenter requested clarification on whether a well ionization chamber (e.g., dose calibrator) was adequate for calibrating low dose rate brachytherapy sources because farmer chambers have historically been associated with § 35.630.

Response. As represented in the Regulatory Analysis accompanying this final rule, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted for the licensee administering brachytherapy doses to ensure that the correct dose is administered to patients. We agree that a well ionization chamber could meet the requirement if the chamber, or source used to calibrate the chamber, is traceable to NIST or an AAPM–accredited calibration laboratory, and a published protocol accepted by a nationally recognized body is used.

Section 35.433, Decay of strontium–90 sources for ophthalmic uses

Issue 1: Were There Any Other Changes Made to This Subpart Between the Proposed and Final Rule?

Response. Yes. The NRC added this new section that requires an AMP to calculate the activity of a strontium–90 (Sr–90) source that will be used in determining the treatment time for ophthalmic uses. It also requires that the activity be calculated using the source activity determined under § 35.432.

We added this section because we are aware of numerous misadministrations involving Sr–90 for opthalmic use that were caused by individuals improperly calculating the decay of sealed sources. Given the risks associated with use of Sr–90 and the numerous misadministrations in this area, a more prescriptive requirement is warranted.

Section 35.457, Therapy-Related Computer Systems

Issue: Were There Any Other Changes Made to This Subpart Between the Proposed and Final Rule?

Response. Yes. The NRC added this new section that is consistent with the requirement found in § 35.657 for therapy-related computer systems. The new section requires brachytherapy licensees who use treatment planning systems to perform acceptance testing on the system in accordance with published protocols accepted by nationally recognized bodies.

Section 35.490, Training for Use of Manual Brachytherapy Sources

General comments on this section are summarized under the General Training topic found at the beginning of this section of the **Federal Register** notice.

Issue 1: Should Training Include Ordering and Inventory of Byproduct Material?

Comment. A commenter requested that we delete the following from work experience requirements: ''ordering'' material safely and ''maintaining running inventories of material on hand.'' The commenter believed that there was no risk associated with these procedures.

Response. Because the AU is responsible for use of byproduct material under the license, the NRC believes that experience in ordering and maintaining inventories of radioactive materials is an important component of a training program for an AU.

Section 35.491, Training for ophthalmic use of strontium–90

Issue 1: Were There Any Other Changes Made in This Subpart Between the Proposed and Final Rule?

Response. Yes. The NRC added this new section. The proposed rule had deleted specific training and experience requirements for individuals who wanted to use Sr–90 for ophthalmic use. Under the proposed rule, these individuals would need to meet the training and experience requirements in the proposed § 35.490 or § 35.940. This change was proposed because, at that time, we believed it was warranted in view of the similarities between the use of Sr–90 eye applicators and the use of sealed byproduct material in medical devices, and recent misadministrations involving Sr–90 eye applicators. Upon further review of the misadministrations, we believe that the majority of the misadministration events could have been prevented if an AMP had calculated the decay of the sources, rather than if NRC required additional training and experience for AUs who want to use Sr–90 for ophthalmic use. Therefore, we added a requirement for an AMP to calculate the activity of the source (§ 35.433) and have included a specific section that provides the training and experience requirements for an individual who would like to use Sr–90 sources for ophthalmic treatments.

This section is identical to § 35.941, Training for ophthalmic use of Sr–90 in the current rule with minor exceptions. We have deleted the phrase ''who is in the active practice of therapeutic radiology or ophthalmology.'' We believe it is important that the individual is a physician and therefore this additional level of prescriptive regulation is not warranted. We have also added a requirement for a written statement, signed by a preceptor AU, stating that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an AU for use of Sr–90 for ophthalmic treatments. This change is consistent with the other training and experience sections within the revised rule. The preceptor statement is discussed in more detail under the General Training topic found at the beginning of this section. Additionally, we have added a provision that a physician who meets the requirements in § 35.490 or equivalent Agreement State requirements would automatically meet the requirements to become an AU under § 35.491.

Subpart G—Sealed Sources for Diagnosis

The NRC received comments on only three areas in Subpart G. They are: (1) SSDR; (2) availability of survey instruments; and (3) training and experience requirements. The first two topics are summarized under the ''Global Changes'' topic in the beginning of this section because the same comments pertain to multiple sections in the rule. Comments on the training and experience requirements are summarized under the ''General Training'' topic found at the beginning of this section.

Subpart H—Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Units

General Comments

Issue 1: Can This Subpart Be Revised To Eliminate Redundant and Overly Prescriptive Requirements?

Comment. A commenter suggested that Subpart H should be rewritten to eliminate redundancy and overprescriptive procedures that the NRC expects licensees to follow. The commenter felt that the licensees should have the ability to develop their own procedures instead of the NRC dictating each step.

Response. The NRC agrees that the rule should not be redundant and we have combined sections whenever possible. For example, in the final rule, we combined § 35.644, Periodic spot-checks for low dose-rate remote afterloaders, with § 35.643, Periodic spot-checks for high dose-rate and pulse dose-rate remote afterloader units. However, the full calibration requirements for all therapy units have been retained in separate sections for each type of unit to avoid confusion on the applicability of certain tests for a given therapy unit.

Subpart H contains requirements for emergency response and operating procedures, including full calibration and spot-check tests. Where warranted by risk, we maintained the prescriptive requirements in the rule. We identified the performance objectives for full calibrations and spot-checks in the rule. This decision was based on various AAPM and ANSI reports. However, the exact content of these procedures has not been specified. These procedures are required to be developed by the licensee and the AMP. Where applicable, the procedures must use published protocols accepted by a nationally recognized body. We believe that this provides the licensee more flexibility in developing its procedures.

Issue 2: How Have National Standards Been Incorporated Into the Rule?

Comment. Commenters were concerned that we are transforming recommended ''practice standards'' into excessively prescriptive and unnecessarily burdensome regulatory requirements.

Response. In many sections, the rule allows licensees to develop their own procedures in accordance with multiple peer-reviewed reports, protocols, or standards. Examples include following recommendations published by the AAPM, ACR, ANSI, and ACMP. The NRC believes this provides licensees with the flexibility needed to develop their own procedures as long as they meet the minimum regulatory requirements in this subpart.

For additional information on the use of consensus standards in the final rule refer to I, Background, in the **SUPPLEMENTARY INFORMATION.**

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC changed the title of this subpart and the language in § 35.600 to make it clear that the requirements in this section refer to only photon-emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Section 35.600, Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

Issue 1: Should All Therapy Sealed Wources Be Required to Have NIST Traceability?

Comment. Some commenters said that all sources used for therapeutic applications should be required by regulation to have a NIST traceable national standard. Conversely, some commenters said that it is inconsistent to require licensees to calibrate such sources in the absence of national standards for all clinically used sources.

Response. Sections 35.632, 35.633, and 35.635 require that sealed source output be measured with a dosimetry system that has been calibrated using a system or source traceable to NIST and published protocols accepted by nationally recognized bodies or by calibration laboratory accredited by AAPM. The NRC agrees with the AAPM position that all therapy sealed sources should be calibrated in accordance with a traceable standard. In limited cases, a traceable standard identical to the therapy sealed source is not available. In these cases, §§ 35.632, 35.633, and 35.635 allow the licensee the flexibility to use protocols accepted by nationally recognized bodies to meet the calibration requirement. As an example, AAPM Report Number 21 recommends that sources used in radiation therapy have calibrations with direct or secondary traceability to national standards. AAPM defines direct traceability as ''when a source or calibrator has been calibrated either at NIST or an AAPM–Accredited Dosimetry Calibration Laboratory.'' AAPM defines secondary traceability as ''when the source is calibrated in comparison with a source of the same design and comparable strength which has direct traceability or when the source is calibrated using an instrument with direct traceability.'' In addition, AAPM TG–56 recommends that for ''sources that do not have a national standard yet, users should develop a constancy check calibrated against the vendor's standard and use this constancy check to verify the source strength. Another option is to develop one's own secondary standard.'' This allows the licensee flexibility in the event that a direct NIST traceable standard does not exist.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added a new paragraph (b) to this section that allows a licensee to use therapy sources in medical research if the research is conducted in accordance with an active IDE application accepted by the FDA and if the requirements in § 35.49(a) are met. This was done to clarify how research with sealed sources could be conducted if the medical use of the sources differed from the statements found in the SSDR for the sources. With this change, we allow previously registered sources to be used for uses other than those described in the original registration process as long as the requirements in paragraph (b) are met.

Section 35.604, Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit

Issue 1: What Is the Purpose of the Survey Required by This Section?

Comment. A commenter requested clarification of the requirement to survey the patient or human research subject and the remote afterloader with a portable radiation detection survey instrument to confirm that the source(s) have been removed from the patient or human research subject and returned to the safe shielded position.

Response. The radiation surveys are needed to ensure that a source does not remain within the patient or outside of the source shield following completion of each treatment with the unit.

Issue 2: Who May Perform the Survey?

Comment. A commenter requested that the rule be revised to allow the medical physicist to train an assistant to do the radiation surveys, required by § 35.604, when the physicist is not available.

Response. The rule does not specify who must perform the surveys required by § 35.604. The NRC believes that the licensee should have the flexibility to decide who should perform the surveys. However, the record of the survey must include the name of the individual who performed the survey, in accordance with § 35.2404.

Section 35.605, Installation, Maintenance, Adjustment, and Repair

Issue 1: Who May Repair a LDR Unit?

Comment. The NRC solicited comments on whether the restrictions in this section on who may work on a device containing a sealed source should apply to LDR units. Some commenters said that the restrictions should apply to LDR units. Other commenters believed that the restrictions should only apply to LDR units if the device manufacturer recommends the restriction for the particular device. Conversely, some commenters said that the restrictions should not apply to LDR units because the risk from these low dose-rate units is minimal enough that a trained individual knowledgeable of the unit's operation could install, perform maintenance, adjust, or repair the device. They believed that we should not ''over-regulate'' these units. Some commenters also believed that users of nonmedical devices who perform these types of services must submit procedures that show they have had appropriate training in performing these services on the specific devices. They stated that persons who perform installation, maintenance, and repair of other NRC-regulated devices (that do not apply radiation to humans) are routinely limited to services on the specific devices for which they have training and experience, e.g., fixed gauges, radiography cameras, etc. In addition, repairs of therapy devices are not just an issue of source or cable replacement, but could also include electronics and software modifications. Consequently, they believed that none of the training and experience requirements identified in the proposed

regulations provide for this kind of training. Therefore, the service provider's specific training must be evaluated by the NRC.

Response. Because of the risk associated with therapy devices, the final rule only allows an NRC or Agreement State licensed entity to install, maintain, adjust, or repair a therapy device that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the therapy unit or the source(s). Additionally, these regulations limit the installation, replacement, relocation, or removal of the sealed source(s) or source(s) in a teletherapy unit, gamma stereotactic radiosurgery unit, HDR, MDR, and PDR, to an entity specifically licensed by the NRC or an Agreement State for these activities. For LDR source(s), the NRC allows an AMP or a specifically licensed entity to perform these functions. This provides relief for licensees possessing LDRs when replacing decayed sources or removing and installing sources to render each individualized treatment plan. However, for work on the LDR source(s) safe, the source(s) driving unit, or other electronic or mechanical components that may expose the source(s) or compromise the radiation safety of the unit, we believe that specialized training, in addition to the training required to meet AMP status, is necessary to perform these activities. Therefore, only personnel specifically licensed by the NRC or an Agreement State may perform these activities.

Issue 2: Does Install, Maintain, Adjust, or Repair Include Assembly?

Comment. A commenter suggested that the word ''assembly'' be added to the list of activities that must be performed by a specifically licensed person.

Response. The NRC believes that ''assembly'' is included within the meaning of installation and repair. Therefore, we made no change in the regulatory text.

Section 35.610, Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Does the Rule Allow Individuals Other Than the Patient To Be Present in the Treatment Room?

Comment. Commenters indicated that therapy administrations in cardiac catheterization suites require the presence of other persons for the safety of the patient during the treatment, and may require that individuals have access to the patient through the treatment room doors without interruption of the treatment. In such cases, the commenters believed that the exposures to personnel were already limited by Part 20 requirements. A commenter also questioned the term ''contraindicated'' in the phrase ''ensuring that only the patient * * * is in the treatment room before initiating treatment with the source(s), unless contraindicated * * *''

Response. The NRC agrees that, in limited cases, the licensee may need to allow other individuals in the treatment room during treatment. We also agree that the scope of ''unless contraindicated'' needs to be defined. Therefore, we modified the final rule to permit individuals approved by the AU, AMP, or RSO to be present in the treatment room, during treatment with the source(s). These individuals are in the best position to determine if an individual may be present in the treatment room during a treatment. However, licensees are still required to control the exposures of workers and members of the public in accordance with Part 20.

Issue 2: Must the Console and the Console Keys Be Secured?

Comment. A commenter suggested that securing both the console and the console keys was redundant. The commenter went on to state that securing a teletherapy or a gamma stereotactic radiosurgery treatment room is unnecessary if the console or console keys are secured because it would be highly unlikely that unauthorized individuals would remove the devices given their bulk and weight. The commenter felt that, in keeping with a performance-based rule, this section should be revised to read ''prevention of unauthorized use or removal of the device when not in use or unattended.''

Response. Paragraph (a)(1) of this section specifies the mechanism for ensuring that the licensed material in therapy treatment devices is controlled when the devices are not attended or are not in use. In keeping with a performance-based rule, the NRC removed the proposed requirement for written security procedures. This allows the licensee flexibility in determining the appropriate method for meeting this requirement. General requirements for security of byproduct material are addressed in Part 20, Subpart I. However, because of the high risk posed by these sources, we believe that a more prescriptive requirement is warranted.

Issue 3: Where Should Emergency Procedures and Instructions Be Posted?

Comment. Some commenters said that requiring a copy of instructions and procedures to be posted only at the device console was too prescriptive. They suggested that the language should be revised to read ''in the immediate vicinity of the device console.'' A commenter also suggested that paragraph (c) of this section was unnecessary because it requires posting the location of the procedures, and paragraph (b) requires the procedures be posted. Another commenter suggested that, in some cases, a console may not exist.

Response. The NRC has not changed either paragraph (b) or (c) in the final rule. Paragraph (b) requires that a copy of the emergency procedures required by paragraph (a)(4) be physically located at the unit console. Paragraph (c) requires posting the location of emergency procedures and the names and telephone numbers of the emergency contacts. Because the emergency procedures for some devices (e.g., HDR units) may consist of several volumes of error codes and their meaning, we do not require that these procedures be posted. However, the actual location (e.g., specific drawer in the console) where these procedures are stored must be posted at the unit console to alert individuals about where to find the detailed emergency procedures in the event of an emergency. We agree that this does not specifically require posting the procedures on the console, but may allow, for instance, posting them on the wall in front of the console. We also believe that a console exists for ''remotely'' delivered sources because the sources must be removed from the source shielding from outside of the treatment room. For cardiac units, this may be an infusion console.

Issue 4: Should Device Operators Be Listed in the License?

Comment. A commenter felt that operator knowledge was vital to prevent a medical event, but the requirements do not address operator education, training, or experience. The commenter suggested that the operator be named in the license.

Response. It is the licensee's responsibility to ensure that operators are trained. In accordance with § 35.27, operators use licensed material and operate licensed devices, depending on the activity being conducted, under the supervision of the AU. Therefore, the NRC does not believe that NRC's prior

review of a specific operator's training is necessary.

Issue 5: What Is the Appropriate Frequency and Scope of Instruction?

Comment. Some commenters suggested that we clarify that persons not receiving annual refresher training are simply prohibited from operating the unit until the training is provided and that the individuals need not be removed from authorization in the institutional license. A commenter also felt that the instruction requirements were too prescriptive for the variety of devices. In addition, while it may be possible to perform a drill simulating the removal of a patient from a teletherapy unit, such a drill is not practical for an HDR unit. The commenter requested that the regulatory text be revised to read ''a licensee shall provide instruction and practice drills or demonstrations, initially and at least annually * * *'' Conversely, some commenters suggested that retraining was not necessary at all because the AMP and the operator routinely perform the procedures.

Response. The NRC amended the regulatory text to clarify the requirements for instruction. We believe that initial instruction and annual retraining are needed to ensure that the correct dose is administered to the patient or human research subject and to ensure that responsible individuals appropriately respond to emergencies. We also believe that emergency drills are appropriate for all devices. The requirement for training on emergency and operating procedures has been revised to clarify that the training provided is ''as appropriate to the individual's assigned duties.'' We believe that the revised rule allows the licensee flexibility in determining the appropriate level of instruction to be provided depending on the level of involvement of personnel in the operation of and emergency response for the therapy unit.

Issue 6: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. In keeping with a more performance-based rule, the NRC removed the requirement for a written procedure for preventing dual operation of radiation producing devices. This allows the licensee flexibility in determining the appropriate method for meeting this requirement.

Paragraph (g) of this section was added to refer licensees to the record keeping requirements in § 35.2610.

Section 35.615, Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Is It Necessary To List the Type and Location of Emergency Response Equipment in the Regulations?

Comment. Commenters believed that the requirement to list the contents of an emergency pack was too prescriptive and confusing. Additionally, commenters believed that the emergency equipment did not need to be specifically located in the patient's room but could be somewhere accessible in the hospital. Commenters felt that the licensee should have the freedom to adequately stock and locate an emergency pack. One commenter also felt that the phrase ''supplies necessary to surgically remove applicators'' kept in the patient's room implied that surgery should be conducted in a nonsterile environment.

Response. The NRC agrees with these comments because, in a performance-based rule, the essential objectives should be stated in the regulation. Therefore, we revised the regulatory text to identify the essential objective of having emergency response equipment available near each treatment room. The list of specific items that are needed for emergency responses has been deleted from this section. The licensee has the flexibility to determine the type of emergency response equipment needed to respond to a source that remains in the unshielded position or is lodged within the patient following completion of the treatment.

We agree that the emergency equipment does not need to be maintained in the treatment room. However, it should be maintained near each treatment room in order to expeditiously respond to an emergency. The final rule allows the licensee some flexibility in locating the emergency response equipment but does not preclude the licensee from placing the equipment in the room. This is especially important in the situation where heavy source shields are needed. The issue of whether to conduct surgical removals of applicators or sources within a treatment room that may not be a sterile environment is left to the licensee's discretion.

Issue 2: Is This Section Applicable to Remote Afterloader Units With Beta-Emitting Sources?

Comment. The NRC solicited specific response on whether the safety precautions in this section should apply to beta-emitting sources. Some commenters felt that the requirements in this section should not apply to remote afterloader beta-emitting sources, since the lower doses from the beta-emitting sources present a very low risk. For example, some commenters felt that paragraphs (b), (c), (d), and (g) could be waived. Other commenters did not believe that we should waive the requirements in this section for remote afterloader beta-emitting sources in keeping with ALARA.

Response. The NRC amended the title of this subpart to make it clear that it only applies to photon-emitting units. We agree that when requirements for beta-emitting remote afterloader units are subsequently added to the regulations, many of the types of requirements described in this section may be appropriate. However, until the use and safety issues of beta-emitting remote afterloader units are fully understood, specific requirements for these units have not been incorporated into this subpart.

Issue 3: Who May Generate a Treatment Plan?

Comment. A commenter suggested adding a requirement that only an AMP may generate an HDR treatment plan. The commenter believed that the level of complexity and the chance for error in this area certainly warranted a requirement in this area.

Response. The NRC has not changed the final rule to state who should generate a treatment plan. We believe that licensees should determine who will generate the treatment plan. Additionally, we remind licensees that under § 35.41, Procedures for administrations requiring a written directive, the licensee must develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directives, including providing the correct dose to the patient.

Issue 4: Is an Intercom System Necessary?

Comment. A commenter requested that the requirement for an intercom system be deleted because voice communication with the patient is not necessary during treatment. The commenter also suggested that the requirement to have an intercom system restricts treatments given by a deaf employee.

Response. Based on ANSI and AAPM recommendations and to help ensure patient and worker safety, the NRC retained the requirement for an intercom system in the final rule. This does not preclude additional use of

another voice activated system that can be used by a deaf operator.

Issue 5: Should the Word ''Expeditious'' Be Used in the Rule?

Comment. A commenter suggested that the term ''expeditious'' in paragraph (e) implies that, if the source is difficult to remove, the licensee will be cited. The commenter also felt that this requirement could interfere with what the physician considers to be in the best interest of the patient.

Response. The potential dose to the patient from a decoupled or jammed therapy source remaining within the patient is significant. Therefore, the NRC has retained the requirement for a licensee to only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

Issue 6: Who Needs To Be Present During LDR Treatments?

Comment. A commenter felt that treatments with an LDR unit should allow for trained individuals, working under the supervision of an AU, who have been trained in the operation of the device to be physically present during treatment initiation and an AU and AMP immediately available. Another commenter felt that the AU and the AMP should be physically present during the initiation of patient treatments involving LDR devices. This commenter also asked whether the reference to a radiation oncology physician includes a resident in training. Still another commenter requested that the NRC delete the requirement for an AU and AMP to be present for continuation of LDR treatments because the treatment may last 48–72 hours and it is not possible to have someone continually available.

Response. In response to public comments, the requirements for the presence of trained personnel during LDR, MDR, and PDR treatments were amended. The final rule does not contain any requirements for the presence of trained personnel for LDR treatments. The risk associated with use of byproduct material in an LDR and manual brachytherapy are similar. Therefore, the NRC does not believe that regulatory text is needed in this area.

For MDR and PDR units, an AMP must be physically present during the initiation of patient treatments and must be immediately available during continuation of the treatments. The final rule allows an AU to permit a physician, working under his/her supervision and with training specific to operation and emergency response for the unit, to be physically present in place of the AU during initiation of patient treatment involving an MDR or PDR unit. The final rule also allows the AU to permit an individual, working under his/her supervision and with training in removing source applicator(s), to be ''immediately available'' in place of the AU during continuation of patient treatment involving an MDR or PDR unit. Because the treatment times for pulsed dose-rate treatments are significantly longer than those for high dose-rate treatments and the activities of pulsed dose-rate sources are approximately one-tenth of the activities of high dose-rate sources, the change in physician attendance during pulsed dose-rate treatments is warranted. Additionally, for normal resumption of treatment controlled by the pulsed dose-rate device during the normal continuation of the treatment, the presence of a medical professional is not required. This revision allows the licensee flexibility in determining the appropriate personnel to have physically present or ''immediately available'' for medical response to patients treated with these units.

Issue 7: Who Needs To Be Present During HDR Treatments?

Comment. Some commenters believed that a physician and a properly trained radiation therapy technologist should be present for HDR treatments. The commenters believed that the responsibility for the device is the AU's, since this is an FDA-approved device. Another commenter believed that the physical presence of an AMP is sufficient if an AU, or a physician trained to respond to an emergency, could be summoned to the HDR unit console within 2 minutes. Some commenters also requested that all remote afterloader requirements be combined because the present requirements are repetitive.

Response. The NRC believes that the requirements for HDR units should differ from the requirements for LDR, MDR, and PDR treatments because the treatment times and the source activities differ significantly. We believe that the requirements appropriately address emergency situations.

An AMP is required to be physically present during the initiation and continuation of all patient treatments involving the unit. The final rule allows an AU to permit a physician, working under his or her supervision, to be physically present in place of the AU during continuation of patient treatment as long as the physician has received operating and emergency response training for the device and as long as the AU is physically present during initiation of the patient treatment. We believe that this revision is appropriate because it allows the licensee flexibility in determining who should be physically present during treatments involving HDR units.

Issue 8: Who Needs To Be Present During Gamma Stereotactic Radiosurgery Treatments?

Comment. A commenter requested that for gamma stereotactic radiosurgery treatments, an AU or anyone trained in the setting of the coordinates and emergency procedures should be present. Another commenter suggested that emergency response could be limited to requiring the presence of a physician capable of dealing with the patient's medical needs and two individuals trained in emergency procedures particular to the unit. Still another commenter suggested that we require continuous monitoring by one trained individual and monitoring by an AU during the start and the end of the treatment.

Response. The NRC requires the physical presence of an AU and an AMP throughout all patient gamma stereotactic radiosurgery treatments to ensure appropriate response to an emergency and to ensure that the correct dose is delivered to the patient.

Issue 9: Were There Aany Other Changes Made in This Section Bbetween the Proposed and Final Rule?

Response. Yes. The NRC amended paragraph (b)(2) to delete the word ''immediately.'' We did not believe the word was needed because the text clearly indicates that the interlock system must cause the sources to be shielded when an entrance door is opened.

We also added a requirement to § 35.615 (f) that an AU and an RSO, or his or her designee, must be notified in the event the patient or human research subject has a medical emergency or dies. This notification requirement is similar to § 35.415(c) and provides consistency in the requirements for therapy devices and manual brachytherapy. In cases where an AU is physically present during the patient treatment, the notification need only be made to the RSO.

Section 35.630, Dosimetry equipment

Issue: Is Calibrated Dosimetry Equipment Needed for Low Dose-Rate Therapy?

Comment. A commenter suggested that licensees routinely do not have or have available, other than through a source provider, calibrated dosimetry equipment that is applicable to the

lower dose-rates used in standard brachytherapy. Therefore, the commenter requested that dosimetry equipment only be required for higher dose-rate procedures.

Response. As noted in the Regulatory Analysis accompanying this final rule, the NRC recognizes that licensees may need to procure additional equipment to meet this requirement. We believe that the additional expenditure is warranted for the licensee administering therapeutic doses to ensure that the correct dose is administered to patients. However, we added regulatory text on the use of the source output or activity determined by the manufacturer so that this section is consistent with the requirements in Subpart F, Manual Brachytherapy. In the final rule, a licensee using an LDR source(s) may rely on the manufacturer's calibration, and hence the manufacturer's calibration equipment, as long as the equipment and source calibration is performed in accordance with protocols accepted by nationally recognized bodies.

Section 35.632, Full Calibration Measurements on Teletherapy Uunits

Issue 1: What Does the Term ''Nationally Recognized Body'' Mean and What Is the Policy for Making Recommendations From These Bodies Into Regulations?

Comment. Commenters questioned what was intended by the term ''nationally recognized body'' and stated that professional protocols may contain items that are recommended but that were never intended to be adopted as regulations.

Response. ''Nationally recognized bodies,'' as used in Part 35, refers both to official standards consensus bodies that are identified on the NIST website and to those professional organizations that develop their reports, protocols, or standards using a consensus process and multiple peer-reviews. Examples of nationally recognized bodies include ANSI, AAPM, ACR, and ACMP. The requirements in this subpart are based on recommendations found in ANSI and AAPM reports and are consistent with the calibration requirements for other sealed sources and devices for therapy. However, the NRC did not include all the recommendations made in the ANSI and AAPM reports nor did we adopt them as regulations because we recognize the prescriptiveness of various reports. Instead, the regulation only contains the essential objectives for the test being required are listed in the rule.

For additional information on the use of consensus standards from nationally recognized bodies, refer to Section I, Background, and the discussion of industry standards in the beginning of this section.

Issue 2: What Is the Meaning of the Term ''Intervals Consistent With 1 Percent Physical Decay''?

Comment. One commenter requested that we clarify whether the requirement meant 1.0000 percent or allowed rounding down to 1 percent. Some commenters felt that 1 percent was too prescriptive because the calibration requirements are higher. Additionally, a commenter requested that the posted values be within 1 percent of the mathematically corrected values.

Response. This section in the final rule requires that outputs be corrected for physical decay at intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides. ''Rounding'' is a mathematical term. ''Consistent with 1 percent'' includes from 0.51 percent to 1.49 percent. The 1 percent correction is separate from the output full calibration. The accuracy of the output full calibration must be within +/-3 percent in accordance with paragraph (b)(1) of this section. This calibration is then used to determine the dose delivered to the patient.

Issue 3: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Accuracy and Linearity?

Comment. Commenters requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. Procedures for calibrating the timer are provided in various protocols, which include tolerances. Examples include ANSI N449 and N449–1, ''Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment'; and AAPM TG–40. As stated in this regulation, the calibration must be performed in accordance with published protocols accepted by nationally recognized bodies. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40. Therefore, the licensee is given flexibility in developing its calibration methods.

Issue 4: Why are repetitive output measurements necessary?

Comment. A commenter agreed with the requirement for full calibration of sources. However, the commenter suggested that repetitive output checks of long-lived sources, such as cesium, was unnecessary because the output is not going to change as long as the source is not leaking.

Response. When delivering a therapeutic dose to a patient or human research subject, the NRC believes that the licensee is responsible for ensuring that the correct dose is administered. Additionally, in accordance with § 35.41, the licensee must implement procedures to ensure that the dose is administered in accordance with the written directive. As part of ensuring that the correct dose is administered, we believe that the source output for all sources used to administer a therapeutic dose must be calibrated and verified. We also agree with published protocols, such as ANSI and AAPM recommendations, that include periodic recalibration of source activity when delivering therapeutic doses. Therefore, we retained the proposed calibration requirements in the final rule.

Section 35.633, Full Calibration Measurements on Remote Afterloader Units

Issue 1: Why Are Repetitive Output Measurements Necessary and Shouldn't the Output Test Requirements Reference the Equipment Calibration Requirements?

Comment. A commenter agreed with the requirement for full calibration of sources. However, the commenter suggested that repetitive output checks of long-lived sources, such as cesium, was unnecessary, because the output is not going to change as long as the source(s) is not leaking. Another commenter suggested that the output calibration requirement should reference the requirement for dosimetry equipment in § 35.630.

Response. When delivering a therapeutic dose to a patient or human research subject, the NRC believes that the licensee is responsible for ensuring that the correct dose is administered. Additionally, in accordance with § 35.41, the licensee must implement procedures to ensure that the dose is administered in accordance with the written directive. As part of ensuring that the correct dose is administered, we believe that the source output for all sources used to administer a therapeutic dose must be calibrated and verified. We also agree with published protocols, such as AAPM recommendations, that

include periodic recalibration of source activity when delivering therapeutic doses. Therefore, we retained the proposed calibration requirements in the final rule. However, for consistency with manual brachytherapy, which is traditionally low dose-rate, we included an allowance for LDR sources in the final rule. Paragraph (f) allows licensees using LDRs to accept the manufacturer's calibration of the unit and source as long as the manufacturer conducted the calibration in accordance with this section and with a published protocol accepted by a nationally recognized body and used a dosimetry system as described in § 35.630(a) to measure the output.

Issue 2: What System Tests and Tolerances Should Be Included in Calibration Requirements?

Comment. Commenters requested the meaning of ''calibrate'' when referencing source guide tubes, connectors, and timer accuracy and linearity. If the purpose is to measure these items to assure they are within some tolerance, the commenters suggested that this purpose be stated in the regulation. Another commenter suggested that timer accuracy is irrelevant to dosimetry as long as the timer functions the same at the time of treatment as at the time of calibration (i.e., consistency), and responds linearly. Some commenters requested deletion of: (1) Timer accuracy and linearity for LDR and PDR units; (2) guide tube calibrations; (3) connector length calibrations; (4) autoradiograph of LDR sources to verify inventory (because sources are difficult to remove from the unit); and (5) battery backup checks (should only be performed at preventative maintenance inspection conducted by the manufacturer). Additionally, a commenter suggested that a reasonable positioning accuracy was 2 millimeters for an HDR stepping source and 5 millimeters for an LDR source (reference AAPM TG–59). A commenter also requested that the NRC clarify that tests for tubes and connectors apply to tubes and connectors in use, and that no tests are required if the unit is not in use.

Response. Various professional reports provide suggested protocols for quality assurance tests on remote afterloaders. The NRC based the performance objectives for various tests in this section on recommendations made by AAPM TG–56. For instance, AAPM TG–56 suggests 1 millimeter positional accuracy for HDR, LDR, and PDR units; initial, annual, and quarterly battery backup checks; timer accuracy tests for LDR units; and autoradiograph of LDR sources. We agree with the recommendations made in AAPM reports and believe that the calibration requirements in this section are warranted to ensure that the correct dose is administered to the patient.

The terminology used in this section was chosen to reflect the current language used in practice. AAPM reports use ''timer accuracy and linearity, applicators, transfer tubes, and transfer tube-applicator interfaces.'' We noted small discrepancies in the terminology used in the proposed requirements versus in AAPM reports. Therefore, we revised the term ''source guide tube'' to ''source transfer tube'' and the term ''connector'' to ''transfer tube-applicator interface'' in the final rule. The tests apply only to units and accessories in use.

Issue 3: How Frequently Should Recalibrations Be Performed?

Comment. A commenter stated that a full calibration is always performed immediately after the source exchange. However, it is probable that the source exchange for an iridium-192 HDR source may take more than 120 days. The commenter suggested that a full calibration on the source after 120 days was not necessary if the source was not yet exchanged for a new source. Another commenter agreed with the proposed requirement that HDR units should be calibrated within 120 days and that LDR units should be calibrated annually, within 1 year. A commenter also requested clarification of the phrase ''not exceeding one quarter.''

Response. The NRC believes that, for iridium-192 (Ir-192) HDR sources, the source calibration frequency can be changed to ''at source exchange'' to allow for source exchanges that slightly exceed the 120-day period. Therefore, the frequency for full recalibration of HDR, MDR, and PDR units has been revised to quarterly for sources whose half-lives exceed 75 days. We believe that this revision will facilitate the use of sources with short half-lives. We also believe that this revision will not reduce safe use of sources whose half-lives are less than 75 days (e.g., Ir-192), because these sources are exchanged at the end of their useful life, which is approximately quarterly for Ir-192. The requirement to perform a full calibration at source exchange has been retained. The phrase ''not exceeding one quarter'' can be equated to a 3-month period.

Issue 4: Who Is Required To Perform the Decay Corrections for Source Output?

Comment. A commenter requested that dosimetrists be allowed to perform decay corrections.

Response. The AMP remains responsible for performing decay corrections because of the high consequence associated with errors in these corrections.

Issue 5: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC deleted the requirement to repeat the full calibration of the remote afterloader unit and source, whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration. We deleted this requirement because the requirement to perform output spot-checks on remote afterloader units was deleted from § 35.643.

We also revised § 35.633(b) to include patient dose delivery components for LDR units that are detailed in AAPM TG–56. Specifically, the requirements in paragraphs (b)(4), (b)(5), (b)(6), and (b)(7) were moved in the final rule so that they apply to all remote afterloaders, including LDRs. The items in these paragraphs are measurement of the length of the source transfer tubes and applicators; measurement of the timer accuracy and linearity over the typical range of use; and function tests of the source transfer tubes, applicators, and transfer tube-applicator interfaces. We believe that these changes are necessary to ensure that, during acceptance testing of the units, including LDR units, and after source replacement, these additional tests that increase patient radiation safety are performed.

Section 35.635, Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

Issue 1: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Accuracy and Linearity?

Comment. Commenters requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section reflects the current language used in practice. AAPM reports use ''timer accuracy and linearity.'' As

stated in this regulation, calibrations must be performed in accordance with published protocols accepted by nationally recognized bodies. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40. Therefore, the licensee is given flexibility in developing its calibration methods.

Issue 2: Can the Licensee Adopt the Manufacturer's Measurements for Relative Helmet Factors?

Comment. A commenter suggested that many users currently adopt the manufacturer's recommended relative helmet factors rather than measure them directly. The commenter stated that this was preferable because: (1) There are inherent difficulties in measuring these factors; (2) requiring users to measure their own factors could result in large errors in some situations; and (3) using the manufacturer's factors aids in sharing information among facilities conducting research protocols.

Response. The NRC believes that measurement of helmet factors is inherent in patient dosimetry. Various professional reports provide suggested protocols for quality assurance tests on gamma stereotactic radiosurgery units. The performance objectives for various tests in this section are based on recommendations in AAPM Report No. 54. For example, AAPM Report No. 54 recommends that helmet factors be measured by the end user. However, in the final rule we changed the proposed requirement for annual measurements of relative helmet factors to require only measurements before the first medical use of the helmet and following any damage to the helmet.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC added the components related to the delivery of the dose to the patient that are in § 35.645, Periodic spot-checks for gamma stereotactic radiosurgery, because all patient dose delivery components detailed in the periodic spot-check section, § 35.645, were not included in the proposed full calibration requirements, and, therefore, were not required during initial quality assurance testing on the unit or after source replacement. The new paragraphs (b)(7) through (b)(10) in the final rule include tests of the treatment table retraction mechanism, helmet microswitches, emergency timing circuits, and stereotactic frames and localizing devices (trunnions). We believe that these changes are necessary to ensure that these additional tests involving patient radiation safety are performed during acceptance testing of the unit and after source replacement. These additions are consistent with the approach used in the teletherapy unit requirements for full calibration and spot-checks.

Section 35.642, Periodic Spot-Checks for Teletherapy Units

Issue 1: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Accuracy and Linearity?

Comment. Commenters requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. Procedures for calibrating the timer are provided in various protocols, which include tolerances. Examples include ANSI N449 and N449–1, and AAPM TG–40. The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40. As stated in this regulation, the measurements must be performed in accordance with procedures established by the AMP. The licensee is therefore given flexibility in developing its spot-check methods.

Issue 2: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (f) was revised to add a reference to the procedures required by paragraph (b).

Section 35.643, Periodic Spot-Checks for Remote Afterloader Units

Issue 1: Is an Output Spot-Check Necessary?

Comment. Commenters requested deletion of the output spot-check because output is calibrated at installation and by the manufacturer, thereby satisfying all the requirements for assuring correct dosimetry and administration. A commenter also suggested that a requirement to determine the output with a dosimetry system described in § 35.630(b) be included.

Response. The NRC agrees that the full calibration output measurements are adequate. Therefore, we have deleted the proposed output spot-check requirement. We believe that a quarterly test for HDR, MDR, and PDR source output and an annual test of LDR source output are sufficient to ensure that the correct dose is delivered to the patient. In the place of the output check, we have included a requirement to check the computer decayed source activity against a precalculated decay chart to confirm that the unit has decayed the source activity properly. The output checks done in accordance with § 35.633 continue to require the use of an appropriate dosimetry system, described in § 35.630, when performing the output calibration.

Issue 2: How Frequently Should Spot-Checks Be Performed?

Comment. Some commenters suggested that the spot-checks be done each day of use, thereby insuring patient safety and not duplicating weekly checks. A commenter requested that the term ''beginning of each day of use'' be revised to ''prior to the use of the device on a given day.'' Another commenter suggested that the frequencies provided in NUREG/CR–6276, ''Quality Management in Remote Afterloading Brachytherapy'', should be used. With regard to timer constancy, a commenter felt that a monthly check was adequate for LDR units.

Response. The regulation has been amended to state ''before the first use of an HDR, MDR, or PDR unit on a given day.'' The NRC developed the frequency of the spot-checks from recommendations of AAPM TG–40 and TG–56, meetings with medical physicists, input from the Therapy Subcommittee of the ACMUI, and NUREG/CR–6276. Therefore, we believe that the frequencies of the spot-checks are appropriate.

Issue 3: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Constancy/Accuracy and Linearity?

Comment. A commenter requested that timer constancy be deleted because it is not a credible source of risk to the patient with the current timer technology. The commenter stated that this is verified at installation and needs no further monitoring. Commenters also requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section was chosen to reflect the current language used in practice. AAPM reports use the terminology ''timer accuracy and linearity.'' The

term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40. As stated in this regulation, the measurements must be performed in accordance with procedures established by the AMP. The licensee is given flexibility in developing its spot-check methods. The NRC has also retained timer checks because they are recommended by the AAPM and are similar to ANSI requirements for teletherapy units. Spot-checks of timer linearity are not required by this section because we believe that timer linearity for remote afterloaders needs only to be measured during full calibration measurements.

Issue 4: Why Must Nonexistent Source Exposure Indicator Lights Be Checked?

Comment. A commenter suggested that checks of source exposure indicator lights be deleted because these lights do not exist on a remote afterloader unit.

Response. The NRC is unaware of any remote afterloader units that do not have source exposure indicator lights. Source position indicator light checks are recommended by the AAPM and are similar to ANSI requirements for teletherapy units. Therefore, these requirements have been retained in the final rule.

Issue 5: Is It Necessary To Perform a Simulated Cycle of Treatment?

Comment. A commenter suggested that the requirement to conduct a simulated cycle of treatment should be deleted because it is vague and will not necessarily provide any higher level of assurance that the remote afterloader unit is working properly than the daily and monthly checks already performed.

Response. The NRC agrees with this comment and has deleted this requirement.

Issue 6: Does a Treatment System Have To Be Locked-Out if the System Fails Safety Tests, But a Backup System Is Available?

Comment. A commenter suggested that the NRC change the wording in this section to be more flexible. The commenter stated that, in some instances, a backup device may be available that will allow patient treatments to continue without compromising patient safety.

Response. This section does not prohibit the use of the unit if the licensee replaces the malfunctioning system before using the unit for treatment. Additionally, the requirement to arrange for prompt repair of a system has been deleted from this section. The NRC believes that the requirement to lock the control console in the off position and not use the unit until repaired is sufficient.

Issue 7: Should Door Interlocks and Audiovisual Systems Apply to LDR Units?

Comment. The NRC solicited specific comment as to whether the requirements for electrical interlocks and audiovisual systems should apply to low dose-rate remote afterloader units. Some commenters felt that LDR units may not require interlocks or audiovisual systems, depending on the dose rate and whether sources are gamma-emitters only. One commenter suggested that we always require interlocks, but require an audiovisual system only when direct visual contact is not available. Another commenter felt that we should always require interlocks and an audiovisual system for LDR units.

Response. The NRC amended the title of this subpart to clarify that it only applies to photon-emitting units. We have retained the requirements for interlocks for LDR units because they are consistent with recommendations in AAPM reports. We have not included a requirement for an audiovisual system for an LDR.

Issue 8: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Paragraph (f) was revised to add a reference to the procedures required by paragraph (b).

Section 35.645, Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units

Issue 1: How Frequently Should Spot-Checks Be Performed?

Comment. A commenter suggested that the requirement for monthly checks be deleted if spot-checks are performed daily. A commenter specified that the term ''beginning of each day of use'' be revised to ''prior to the use of the device on a given day.'' Another commenter suggested that the frequencies provided in NUREG/CR–6324 should be used. Other commenters said that: (1) A daily output measurement was not necessary as long as the user checks the mechanical integrity of the system through a standard run; and (2) the manufacturer recommends that the battery backup system only be tested on a monthly basis.

Response. The regulation has been amended to state ''before first use of the unit on a given day.'' The NRC developed the frequency of the spot-checks from recommendations of AAPM Report No. 54, meetings with medical physicists, input from the Therapy Subcommittee of the ACMUI, and NUREG/CR–6324, ''Quality Assurance for Gamma Knives.'' We believe that the final rule distinguishes between the checks that must be done daily or monthly. Additionally, the final rule only requires output checks and battery backup checks monthly. Therefore, we believe that the frequencies of the spot-checks are appropriate.

Issue 2: Define ''Assure Proper Operation of Stereotactic Frames and Localizing Devices?''

Comment. A commenter requested that we clarify what is meant by ''assure proper operation of stereotactic frames and localizing devices.''

Response. Various professional reports provide suggested protocols for quality assurance tests on gamma stereotactic radiosurgery units. For instance, reports from AAPM, ACR, ACMP, and ANSI may be used by the licensee in performance of these tests. The phrase ''assure proper operation of stereotactic frames and localizing devices'' means to perform quality assurance tests on these devices to assure that they operate appropriately when used to deliver a dose to a patient. The measurements must be performed in accordance with procedures established by the AMP. The licensee is, therefore, given flexibility in developing its spot-check methods.

Issue 3: What Is the Meaning of the Term ''Calibrate'' When Referring to Timer Accuracy and Linearity?

Comment. Commenters requested the meaning of ''calibrate'' when referencing timer accuracy and linearity. The commenters suggested that, if the purpose is to measure these items to assure they are within some tolerance, this purpose should be stated in the regulation.

Response. The terminology used in this section reflects the current language used in practice. AAPM reports use ''timer accuracy and linearity.'' The term calibrate, as used in this context, means to perform measurements to assure that the timer is operating appropriately within a given tolerance. The tolerances may be found in reports such as AAPM TG–40 The measurements must be performed in accordance with procedures established by the AMP. Therefore, the licensee is given flexibility in developing its spot-check methods.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC deleted the requirement to check the hydraulic cutoff mechanism because we believe that checking the hydraulic backup system monthly is sufficient.

We revised the regulatory text to make the spot-checks, and associated corrective actions, consistent with the requirements in §§ 35.642 and 35.643. Paragraph (b)(1) requires that licensees perform spot-checks in accordance with written procedures established by the AMP. Paragraph (b)(2) requires that the AMP review the results of the spot-checks within 15 days and notify the licensee as soon as possible in writing of the results of the spot-checks.

Paragraph (g) was revised to add a reference to the procedures required by paragraph (b).

Section 35.647, Additional Technical Requirements for Mobile Remote Afterloader Units

Issue 1: What Are the Requirements for Discontinuing Use of a Malfunctioning Unit?

Comment. A commenter noted that this section did not contain a requirement for discontinuation of use of a malfunctioning unit and questioned whether this was an oversight.

Response. The NRC agrees with this comment. We believe that a licensee using a mobile unit must also meet the requirements described in other sections of this subpart applicable to the particular device in use. However, for clarification, we added language that prohibits the use of the unit if a safety check is failed. Paragraph (d) now reads: ''If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.''

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. Consistent with the terminology used in § 35.633, ''connectors'' was revised to ''source transfer tubes, and transfer tube-applicator interfaces.''

Section 35.652, Radiation Surveys

Issue 1: Are These Surveys Limited to Therapy Units?

Comment. A commenter questioned whether the surveys required by this section were only for therapy devices or if they included other instruments or devices used at medical facilities.

Response. The requirements of Part 35 apply only to medical uses of byproduct material. The requirements in this section apply to licenses issued for uses in this subpart. Therefore, these requirements do not include sealed sources covered by other subparts (e.g., Subparts F and G). The NRC added the phrase ''licensed under this subpart'' to this section to clarify this issue.

Issue 2: Why Do Radiation Levels Around Devices Differ?

Comment. Commenters suggested that the maximum radiation levels and average radiation levels around devices could be made a generic number, as with radiography cameras and source changers. They also suggested that it may make sense to put in the average acceptable reading for each type of afterloader unit (i.e., high dose-rate, low dose-rate, and pulsed dose-rate units).

Response. The radiation levels referenced in the SSDR differ greatly by device manufacturer. Therefore, the NRC retained the requirement in paragraph (a) of this section ''to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.''

Section 35.657, Therapy-Related Computer Systems

Issue 1: What Is the Purpose of Acceptance Testing on Computer Operating Systems?

Comment. Commenters felt that acceptance testing of computer operating systems should be deleted because no method could guarantee that software would always operate appropriately. A commenter also said that this requirement should be deleted because it appears to be a year 2000 concern with operating systems.

Response. The NRC agrees with these concerns and has deleted the requirement to verify operability of computerized operating systems. This concern is addressed by the FDA's regulations of medical devices, which require reliability testing on computerized operating systems.

Issue 2: Should Acceptance Testing of Treatment Planning Systems Be a Requirement?

Comment. Commenters believed that the requirement for treatment planning system acceptance testing was warranted. However, they suggested that the methodology for acceptance testing should be left to the licensee. The commenters also questioned the ability to guarantee that the systems are operating appropriately and questioned our interest in the device operating system that is reviewed by the FDA.

Response. Paragraph (a) of this section in the proposed rule would have required the licensee to verify that the computerized operating system and treatment planning system are operating appropriately. Based on these comments, FDA's review of reliability testing on medical devices, and the device's associated computer operating systems, the NRC deleted these requirements from the final rule.

We agree with commenters that treatment planning system acceptance testing is warranted. Therefore, the requirement to perform acceptance testing on treatment planning systems has been retained. We believe that this requirement is appropriate and still provides the licensee flexibility in designing its acceptance testing program. We amended the regulation to incorporate the components of acceptance testing addressed in AAPM TG–56. The licensee is provided flexibility in performing acceptance testing of treatment planning systems as long as a published protocol accepted by a nationally recognized body is used and as long as the minimum testing requirements are met.

Section 35.690, Training for use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

*Response.*Yes. The NRC revised paragraph (b)(3) to read ''an authorized user of each type of therapeutic unit for which the individual is requesting authorized user status.'' This change clarifies that the preceptor authorized user must certify that the individual has achieved a level of competency sufficient to function independently as an authorized user for each type of unit for which the individual would like authorized user status. However, this does not mean that the individual has to satisfy paragraphs (b)(1) and (b)(2) in their entirety for each type of unit, e.g., an individual does not need 1400 hours in a structured educational program if he or she wants to be an AU for two types of units under § 35.690.

In paragraph (b)(3) we also clarified that the preceptor AU must be an AU for each type of unit for which he or she is a preceptor.

General comments on this section are summarized under the General Training topic found at the beginning of this section.

Subpart J—Training and Experience Requirements

Issue 1: Why are There Two Sets of Training and Experience Requirements in the Revised Part 35?

Comment. One commenter noted that much of Subpart J is redundant with, but not identical to, the training and experience requirements listed in the individual sections of the other subparts. The training and experience requirements should be identical if they are included in 2 subparts within the same part, or they should only be listed once in the part.

Response. The NRC believes that Subpart J should be retained for a 2-year transition period as stated in the proposed rule (63 FR 43516; August 13, 1998). The issue of recognition of medical and other specialty boards was discussed during an ACMUI briefing of the Commission on February 19, 2002. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and may not be ready to apply for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel because many license authorizations are granted based on recognition of board certification. The Commission has considered this matter, and decided to retain the current training requirements in Subpart J for a 2-year period after the effective date of the final rule. As stated in Section IX, Implementation, during that 2-year period, licensees will have the option of complying with either the requirements of Subpart J or the requirements in Subparts B and D–H. During this transition period, the NRC will continue working with the ACMUI and the medical community to resolve any concerns with the training and experience requirements.

The Commission will consider changes to the training and experience requirements, as appropriate.

Individuals who have status as AUs, AMPs, ANPs, and RSOs at the time the rule becomes effective will be ''grandfathered'' under § 35.57, and will not have to satisfy the new training and experience requirements. For additional information on the ''deemed status'' of individuals when the final rule becomes effective refer to the general discussion of the training and experience requirements at the beginning of this section.

Issue 2: Why Were the Lists of Certifying Medical Boards in Subpart J of the Current Part 35 Not Updated During the Rulemaking to Include Other Medical Specialty Boards and Other Subspecialties?

Comment. Several commenters noted that there are other medical specialty boards and other subspecialties that should be added to the lists of certifying boards in Subpart J.

Response. The suggested updates were not made in the final rule because Subpart J will be retained for 2 years after the effective date of the final rule and there are no lists of certifying specialty boards in the new training and experience requirements in Subparts B and D through H of Part 35. Under the new regulations, the NRC will continue to review the appropriate training and experience requirements of the boards and recognize the boards that satisfy these requirements. However, we will provide the lists of recognized boards in a public document (e.g., on NRC's Internet site <www.nrc.gov>), rather than in the regulations. Before the effective date of the final rule, we encourage the certifying boards to submit their applications for recognition under the new regulations. However, the licensees will have 2 years after the effective date of the final rule to comply with the new requirements. For additional information on the recognition of specialty boards refer to the general discussion of the training and experience requirements at the beginning of this section.

Issue 3: Why Have the References to ACGME programs been retained in Subpart J?

Comment. Several commenters said that all references to ACGME programs of less than 2 years should be deleted.

Response. The NRC deleted the references to ACGME programs of less than 2 years.

Issue 4: Why Are There No Training Requirements for Endovascular Brachytherapy in Subpart J?

Comment. One commenter noted that Subpart J includes no training requirements for endovascular brachytherapy.

Response. The NRC will delete Subpart J 2 years after the effective date of the final rule. When the research on endovascular brachytherapy is completed, the standard protocol for this technology will be evaluated to determine if it is similar to the modalities currently licensed under Part 35 or if it should be licensed as an emerging technology under § 35.1000. Following this determination, the training and experience requirements for this modality will be evaluated to see if new requirements are needed for this use or if it should continue to be regulated as a sealed source therapy.

Section 35.981, Training for Experienced Nuclear Pharmacists

Issue 1: What is the Impact of Deleting This Section?

Comment. All of the commenters that responded to this question, which the NRC asked in the proposed rule, said that this section could be deleted because the requirements in § 35.57 for an experienced nuclear pharmacist are adequate.

Response. This section will be deleted, along with the other sections of Subpart J, 2 years after the effective date of the final rule.

Subpart K—Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

Section 35.1000, Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

Issue 1: What Is the Purpose and Scope of This Section?

Comment. There were a number of general comments on this section. Comments ranged from an endorsement of the need for this section to concerns that NRC's regulations for emerging technologies will limit the use of new technologies and radiopharmaceuticals and, consequently, affect the delivery of high quality health care.

Some commenters believed that the purpose of this section is vague, undefined, and confusing, and that there needs to be a clearer definition of an emerging technology. One suggestion was that the definition be tied to whether an IND/IRB approval is required. Another commenter said that this section should specifically exempt radiopharmaceuticals because they are regulated by the FDA under RDRC, new drug applications (NDA), biologic product license applications (PLA), and INDs. Thus, all radiopharmaceuticals should fit under Subpart D or E.

One commenter said that emerging technology uses should be reviewed on a case-by-case basis to determine their proper location in the regulations. The commenter proposed a process to determine how an emerging technology should be regulated: propose performance-based regulations for a 90-day comment period; locate the regulations in a separate subpart; and

establish that any technology placed in this subpart would have a 5–7 year sunset period at which time the regulations for this technology would be relocated in another appropriate subpart. This process would provide the opportunity for the technology to establish itself and allow the regulations to be amended, based on observed risk.

Response. The NRC added Subpart K to Part 35 so that there would be codified regulatory requirements and a more clearly defined process to obtain a license, or a license amendment, for a new medical use of byproduct material or radiation from byproduct material, i.e., an emerging technology. By adding requirements for emerging technologies to the regulations in §§ 35.12(d) and 35.1000, an applicant for a medical use that does not fit the regulatory requirements for another subpart knows the type of information to submit to NRC.

The scope of this subpart includes all new medical uses of byproduct material or radiation from byproduct material. We have not attempted to define what is included in this subpart or what is excluded from this subpart more clearly because there is no way to predict what types of medical technologies will be developed in the future. The Commission, with input from the ACMUI, as requested, will determine if the emerging technology is truly a new technology and is covered by Subpart K, or if the ''new'' technology is actually a type of use regulated under Subparts D through H.

Issue 2: What Process Will Be Used to Establish Regulatory Requirements and Evaluate Applications for Emerging Technologies?

Comment. Commenters stated that it is important to have a reasonable regulatory scheme and time frame for approving applications for new technologies. Some commenters expressed concerns about placing so much regulatory burden (e.g., too many safety constraints) on new technologies that there is an impact on the development of new products.

Emerging technologies have an undefined risk. Once the risk becomes clear, the degree of regulation that is needed to minimize the risks to the public can be defined. The NRC might be interested in the design of trials involving emerging technologies, and what kind of data are collected, in order to define the risks from emerging technologies.

A model was suggested for establishing the requirements for emerging technologies. Under the suggested model, appropriate professional societies would establish task forces to examine the issues (e.g., the training requirements) associated with the emerging technology. This model was successful in defining the standards for gamma stereotactic radiosurgery in the late 1980's when it was considered an emerging technology.

Response. The NRC agrees with these comments and will take them into consideration in setting up the process for establishing regulatory requirements and for approving applications for emerging technologies. We intend to evaluate each technology on a case-by-case basis and to work with the ACMUI, the medical community, the public, and the developers of the new technology, as appropriate, to determine the specific risks associated with the technology and any additional regulatory requirements for the medical use of the technology.

Issue 3. Will the NRC Coordinate its Regulations for Emerging Technologies With the FDA's Regulations?

Comment. One commenter has observed that the FDA process works well in addressing patient safety for investigational new drugs and devices. This commenter suggested that the NRC communicate its concerns to the FDA to assure that any radiation safety issues will be included and documented in the investigational research process.

Response. The NRC does not intend to develop requirements that are redundant with those of the FDA. FDA and NRC have different authorities and responsibilities for protection of public health and safety; FDA has the authority to approve investigational new drugs and devices; and NRC has the authority to protect the public, workers, and patients from the medical use of byproduct material. However, we have a ''Memorandum of Understanding'' with FDA under which we coordinate certain agency functions and share information (58 FR 47300; September 8, 1993 and 62 FR 15740; April 2, 1997, renewal).

Issue 4: Why Does This Section Not Include Training and Experience Requirements for AUs of Emerging Technologies?

Comment. Several commenters said that this section should provide the minimum criteria and training requirements for AUs of these new medical uses. The qualifications of individuals to use emerging technologies are pretty well established by the developers of the emerging technology, and they are aware of the radiation safety problems associated with the new technology. Whether it is an emerging technology or not, there is a need to understand the properties and hazards of the radioactive material being used, the radiobiological issues, and the measures to be taken in the event of a spill, and to demonstrate the ability to safely handle the radioactive material.

Response. Section 35.1000 does not include any training and experience requirements for AUs of emerging technologies because there is no way of knowing what training requirements will be necessary for the safe use of byproduct material in new technologies. Applicants are required by § 35.12(b) to provide the training and experience for the AU, ANP, or AMP, as appropriate, to the NRC. The training and experience will be evaluated on a case-by-case basis with input from the ACMUI and individuals who have been involved with development of the technology, as needed, and other input, as appropriate.

Issue 5: Will Cost Issues Be Considered During the Development of Requirements for Emerging Technologies?

Comment. Comments were provided on several different cost issues. One commenter said that it is very difficult to spend millions of dollars on clinical research on new technologies and have no idea what the regulatory requirements are going to be. Another commenter said that cost effectiveness needs to be considered during the development of requirements for new technologies. For example, a requirement to have multiple professionals present during a procedure would not only increase the cost of the procedure, but would also limit its availability to patients.

Response. Licensing requirements for emerging technologies will be based on the risk posed by the specific modality and when possible licensing requirements will be modeled on other medical uses with similar risk. In order for new or revised requirements to be codified in Part 35, a public rulemaking process under the Administrative Procedure Act must be followed including the development of a cost-benefit analysis made available for public comment.

Issue 6: Will Intravascular Brachytherapy Be Considered an Emerging Technology in the Revised Part 35?

Comment. Some commenters believe that intravascular brachytherapy is still experimental and covered by § 35.6 and need not be considered in § 35.1000. Other commenters believe that intravascular brachytherapy should be categorized, or specifically mentioned, as an emerging technology under the provisions described in § 35.1000.

One commenter stated that in the proposed rule the standard use of radioisotopes in patients in the field of cardiology was reclassified as experimental and cardiologists had become radiation oncologists.

Response. Section 35.6 contains some specific provisions for protection of human research subjects and does not permit the use of byproduct material for medical uses that are not authorized on the licensee's medical use license. Intravascular brachytherapy is a very complex field with a number of methodologies and radionuclides being evaluated for use. Currently, the NRC is regulating intravascular brachytherapy as a sealed source therapy. Because no single standard protocol for intravascular brachytherapy has been established, the Commission, with input from the ACMUI, the medical community, and the public, will review the technology in light of that protocol to determine if new regulatory requirements are needed for this use. Pending development of those regulatory requirements, an applicant will be able to submit a license application or amendment request, under the provisions of §§ 35.12 and 35.1000, to incorporate the new modality into their licensed program.

Issue 7. What Are the Training and Experience and Radiation Safety Requirements for Intravascular Brachytherapy?

Comment. Some commenters felt that intravascular brachytherapy should have the same training and radiation safety requirements as the rest of radiation oncology. Other commenters felt that the training and radiation safety requirements for nuclear cardiology should be reserved until the technology advances enough to develop standard protocols with the assistance of a group of experts. Still other commenters stated that the NRC should develop the training and safety requirements for intravascular brachytherapy.

Response. As we noted in Issue 6, intravascular brachytherapy is currently an evolving medical treatment composed of diverse technologies. Currently, the NRC is regulating intravascular brachytherapy as a sealed source therapy with the associated training and experience requirements for that therapy. The types of sources used vary widely in terms of the type of radiation emitted, the activity, and the level of encapsulation. In fact, intravascular brachytherapy may not evolve into either a standard protocol or a single modality. Pending receipt of additional information, we believe that it is too early to make changes in the level of training and experience for the use of intravascular brachytherapy.

Issue 8: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response: Yes. The NRC corrected the wording in paragraph (a) to state that the information that is required to be submitted by an applicant for use of byproduct material under § 35.1000 is in § 35.12(b) through (d), not only in paragraphs (b) and (c).

We amended the wording in paragraph (b) to reflect a change in § 35.12(d) that allows licensees to submit an application for a license amendment, rather than an application for a separate license, for use of byproduct material under § 35.1000. This change is discussed under § 35.12.

Subpart L—Records

Issue 1: Should All the Recordkeeping Requirements Be Grouped Into One Subpart or Should They be Incorporated Into the Section Requiring the Record?

Comment. Commenters provided a wide range of responses to the Commission's question on whether all of the recordkeeping requirements should be grouped into one subpart, or whether they should be incorporated into the individual sections requiring the records. Some commenters favored having all of the recordkeeping requirements in one subpart because this format provides for easy reference, simplifies licensing, assists licensees in meeting their obligations for the radiation safety program, and simplifies compliance. Other commenters favored having the recordkeeping requirements in the individual sections because this format would place all of the requirements pertaining to a particular area of interest in one section. Therefore, licensees would know exactly what was expected of them in a particular area. They also find the similar separation in 10 CFR Part 20 to be confusing. Several commenters preferred a ''balanced approach'' in which the recordkeeping requirements would be in the individual sections and then all of the requirements would be summarized in a separate subpart.

Response. After reviewing all of the responses to this question, the NRC concluded that having all of the recordkeeping requirements in one subpart makes it easier for licensees to reference these requirements. However, the final rule is consistent with the ''balanced approach'' because each section in the final rule that is associated with a recordkeeping requirement includes a cross-reference to the specific recordkeeping requirements in Subpart L.

Issue 2: Are All of the Recordkeeping Requirements in Part 35 Needed?

Comment. Comments on the need for the recordkeeping requirements in Part 35 ranged from all of the records are needed; to the only records that are needed are those that document overexposures, exceeding environmental limits, and leaking sources; to the only records that should be required are those that have a documented history of improving radiation safety; to none of the records are needed.

Response. During preparation of the final rule, each specific recordkeeping requirement was reviewed in light of these comments and changes were made, where appropriate. These changes are noted in the discussions of the individual recordkeeping sections.

Issue 3: Are the Recordkeeping Requirements too Prescriptive?

Comment. The recordkeeping requirements in the proposed revision maintain the detailed, prescriptive elements that are in the current Part 35.

Response. All of the elements in the recordkeeping requirements in the proposed rule were considered important for documenting radiation safety issues associated with a more risk-informed regulation. During preparation of the final rule, the NRC reviewed each recordkeeping requirement in light of this comment and made appropriate changes.

Issue 4: Why Are There Different Retention Periods for the Records Required by This Subpart?

Comment. One commenter said that compliance with NRC's recordkeeping requirements would be simplified if all of the record retention periods were the same. Another commenter suggested that because most of the records have a retention period of 3 years, it would make more sense to include a separate section that states that all of the records in this subpart are to be maintained for 3 years, unless otherwise stated, than to restate the retention period in each section.

Response. The record retention periods in Part 35 were set according to either the safety significance of the action being recorded or the inspection frequency. As a result, there are several different retention periods for records in Subpart L. Because record retention periods are tied to safety considerations, the NRC believes that the regulations should specifically state the retention period for each recordkeeping

requirement even if it means repeating regulatory text.

Issue 5: How Can a Patient's Privacy and Confidentiality be Protected in Records Required by NRC?

Comment. A comment received stated that the patient's privacy and confidentiality are ''ignored'' with NRC recordkeeping requirements for records of the patient's name, social security number, and other personal information.

Response. Any records that must include the patient's name or personal information relating to the patient are to be retained by the licensee. Reports relating to medical events, which licensees provide to the NRC, explicitly must not contain the individual's name or any other information that could lead to identification of the individual.

Issue 6: Can Initials Be Used on a Record To Identify the Individual Who Performs an Activity or an Operation?

Comment. The requirement to record the ''name of the individual'' that performed a certain activity appears throughout this subpart. Several commenters said that because it is common practice to utilize initials as identifiers of individuals, the words ''name of the individual'' should be replaced with ''identification of the individual.''

Response. The NRC requires that the full name of an individual appear on a record to better ensure future identification of the individual who performed the activity or operation. It is not uncommon for several individuals to have different names, but the same initials. Also, initials are more likely to be illegibly scribbled.

Issue 7: Why Do Some Records Require a Signature, Rather Than the Name of the Individual?

Comment. Several commenters said that requiring a signature on a record is prescriptive, not performance based, and does not necessarily mean that an individual has actually read or reviewed a record.

Response. The NRC has required signatures only on those records where we feel it is important to the radiation safety program to document who approved the action, reviewed the report, performed the calibration, etc. If an individual signs a record saying, for example, that he or she performed an action, we assume that the individual actually did perform whatever action was required and is in compliance with the recordkeeping requirements in this part. Note that most of the recordkeeping requirements in Subpart L require the name of the individual, rather than a signature.

Issue 8: Do the Recordkeeping Requirements in Part 35 Allow for the Use of Electronic Signatures?

Comment. Some commenters were concerned that the requirements for signatures preclude maintaining records electronically.

Response. Section 35.5, Maintenance of records, allows records to be maintained electronically. Therefore, electronic signatures are permitted.

Section 35.2024, Records of Authority and Responsibilities for Radiation Protection Programs

Issue 1: Can the Requirements in This Section Be Made Less Prescriptive and Therefore Less Burdensome on Licensees?

Comment. Several commenters felt that the requirements in this section are too prescriptive and burdensome, especially for private practices with one physician who is also the owner/president and RSO.

Response. The NRC has retained the requirements in this section because we believe that records associated with the authority and responsibilities of the radiation protection program are fundamental to the safe use of byproduct material by all medical licensees, regardless of their size. Even single practice physicians, who may also serve as RSOs, need to be well aware of and to document their authority, duties, and responsibilities associated with being the RSO named on either an NRC or Agreement State license.

Issue 2: Why is It Necessary for Licensees to Retain Records of the Licensee's Management's Written Approval of Actions Associated With the Radiation Protection Program for 5 Years?

Comment. One commenter said that the requirement in paragraph (a) of this section to retain records for 5 years is excessive.

Response. The NRC considers the records required by paragraph (a) of this section to be important in documenting actions taken by the licensee's management that affect its radiation protection program. These records include requests for a license application, renewal, or amendment; approval of AUs, AMPs, and ANPs; and radiation protection program changes that do not require a license amendment. The 5-year retention period will ensure that the records that are key to a licensee's radiation protection program are available for review during inspection of medical use licensees. During the development of the proposed rule, we evaluated the retention period for this requirement and changed the retention period from the duration of the license to 5 years. Therefore, the recordkeeping burden for licensees to comply with the requirements in this paragraph is less than the burden to comply with the current rule.

Issue 3: Why is it Necessary for Both Licensee Management and the RSO to Sign the Authorities, Duties, and Responsibilities of the RSO?

Comment. Several commenters said that the requirement in paragraph (b) of this section for both licensee management and the RSO to sign the authorities, duties, and responsibilities of the RSO was too prescriptive. They felt that it was unnecessary to require the signature of both of them because other sections only require one signature or name. One commenter was also concerned that, if a problem occurred, the written agreement could be used by licensee management against the RSO.

Response. The NRC retained the requirement for signatures of both licensee management and the RSO because we believe it is important that there is a signed record of what the licensee management and the RSO agree are the authorities, duties, and responsibilities of the RSO. If both the licensee management and the RSO have a clear understanding of the responsibilities of the RSO for the licensee's radiation protection program, problems such as that referred to in the comment could be avoided. We explicitly state in this section that the signed document, as required by § 35.24 (b), and the responsibilities of the Radiation Safety Officer, as required by § 35.24 (e), must be retained for the duration of the license. This retention period is identical to the retention period specified in § 30.51(b), which would otherwise apply. However, without this explicit statement in Part 35, the licensee would have to reference the general recordkeeping provisions in § 30.51 for the record retention period.

Section 35.2026, Records of Radiation Protection Program Changes

Issue 1: Why is There a Requirement for Retaining Records of Changes to a Licensee's Radiation Protection Program that ''Do Not Reduce Safety,'' and Why Must These Records Be Signed by Licensee Management?

Comment. Commenters said that it is excessive and unnecessary to retain

records of radiation protection program changes that do not reduce safety. In addition, the commenters believed that it is unnecessary to have licensee management sign the records of radiation protection program changes that had already been reviewed and signed by the RSO, the licensee's radiation safety expert.

Response. Licensees are required to obtain Commission approval for changes in their radiation protection program, except for the revisions authorized by § 35.26. Because licensees are not required to submit these latter changes to NRC for approval, the records of the changes made in accordance with § 35.26 provide the Commission an opportunity to evaluate these changes during the inspection process. The NRC believes that this approach is warranted in light of the importance of changes in a licensee's radiation protection program.

The reference in proposed § 35.26(a)(2) to changes that ''do not reduce radiation safety'' resulted in many comments that this phrase was ''ambiguous'' and ''subjective.'' The proposed wording was intended to provide the licensee with as much flexibility as possible in making changes in its radiation protection program, without seeking Commission approval. However, because commenters felt that the proposed wording was not clear, we revised the text of paragraph (a)(2) to state the more objective parameter of changes that are ''in compliance with the regulations and the license.''

We have deleted the requirement in § 35.2026 for the RSO to sign the records of radiation protection program changes because licensee management is ultimately responsible for the radiation protection program. Therefore, the final rule includes a requirement for licensee management to sign these records.

Issue 2: Can the Requirements in This Section Be Made Less Prescriptive and Therefore Less Burdensome on Licensees?

Comment. Several commenters noted that the recordkeeping requirements in this section are quite prescriptive and suggested that the sentence with the list of items that must be included in the records be deleted or revised to be less prescriptive.

Response. The NRC believes that the recordkeeping requirements in this section are needed to document what changes have been made in the licensee's radiation protection program. We considered the burden on licensees during development of the final requirements for this section and believe that the requirements for radiation protection changes, and the associated records, provide the licensee more flexibility to manage its radiation protection program than in the current rule and reduce the recordkeeping burden on licensees. For example, licensees must currently retain a record of each radiation protection change until the license has been renewed or terminated. Under the final rule, licensees are only required to retain these records for 5 years.

Issue 3: Why Are Licensees Required To Retain a Copy of the Old Radiation Protection Procedures?

Comment. One commenter questioned the need to retain a copy of the old radiation protection procedures because they are immaterial to the current procedures and could be confusing to workers.

Response. The NRC believes that licensees should retain a copy of their old radiation protection procedures for 5 years so that they are available during the licensee's next inspection after the procedures were changed. If a ''problem'' or ''event'' is discovered during an inspection, the radiation protection procedures that were in place at the time of the event may be very useful in determining the cause of the event.

We suggest retaining the copy of the old radiation protection procedures in the licensee's filing system so that they are not readily available for workers to refer to by mistake.

Issue 4. Were There Any Other Changes Made In This Section Between the Proposed and Final Rules?

Response. Yes. The word ''safety'' was removed from the title of this section. This change has been made to correct an inconsistency between the regulatory text in this recordkeeping section and the corresponding § 35.26, Radiation protection program changes.

Section 35.2040, Records of Written Directives

Issue 1: Is There a Need for an NRC Requirement to Retain a Copy of Written Directives for Therapeutic Administrations of Unsealed Byproduct Material?

Comment. One commenter said that the requirement for retaining a copy of written directives should exempt radiopharmaceuticals because state laws already require retention of prescription records.

Response. Section 35.40, Written directives, contains a list of items that must be included in a written directive and requires that an AU sign and date the written directive before administration of sodium iodide I–131 greater than 1.11 MBq (30 μCi) or any therapeutic dosage of unsealed byproduct material. In other words, this section includes specific requirements for preparing written directives before administering higher dosages of unsealed byproduct material. Prescriptions for radiopharmaceuticals may or may not be signed by AUs and may or may not include all of the items that are required by § 35.40 for written directives for administrations of therapeutic dosages of unsealed byproduct material. The NRC believes that retaining copies of written directives will help ensure that administrations of therapeutic dosages of unsealed byproduct material are in accordance with the written directives. In addition, a copy of the written directive may be useful in evaluating whether a medical event was a result of a generic problem that may also affect other licensees.

Section 35.2041, Records for Procedures for Administrations Requiring a Written Directive

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. This section was added to the final rule. We explicitly state in this section that the procedures required in § 35.41 (a) must be retained for the duration of the license. This retention period is identical to the retention period specified in § 30.51(b), which would otherwise apply. However, without this explicit statement in Part 35, the licensee would have to reference the general recordkeeping provisions in § 30.51 for the record retention period.

Section 35.2045, Records of Medical Events

Issue 1: Can the Requirements in This Recordkeeping Section Be Made Less Prescriptive and Therefore Less Burdensome on Licensees?

Comment. One commenter noted that the recordkeeping requirements in this section are quite prescriptive and suggested that the list of items that must be included in the records be deleted.

Response. Section 35.2045 has been deleted in the final rule. Since licensees are required to report information about medical events to the NRC under § 35.3045, we believe that it is not necessary to require licensees to retain a record of this information under § 35.2045.

Issue 2: Should There Be a Requirement for Maintaining Records of Significant Precursor Events?

Comment. One commenter opposed the recordkeeping requirement for significant precursor events.

Response. There are no recordkeeping requirements for significant precursor events in the final rule because there are no requirements for reporting precursor events.

Section 35.2060, Records of Calibrations of Instruments Used To Measure the Activity of Unsealed Byproduct Material

Issue 1: Does This Section Address ''Calibrations'' or ''Performance Checks''?

Comment. A commenter recommended that the word ''calibrations'' be replaced with the term ''performance checks'' because the commenter believes that the tests required by the section are more accurately defined as performance checks.

Response. The NRC did not adopt this comment because this section addresses calibration of all instruments used to measure the activity of unsealed byproduct material, including dose calibrators. We believe this is the appropriate term because the term ''calibration'' is commonly used within the radiation protection profession.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC changed the title of this section to state more accurately that it addresses the calibration of instruments used to measure the activity of unsealed byproduct material. In addition, we deleted prescriptive requirements from § 35.2060. This change is consistent with the revisions made to § 35.60. The licensee is only required to record the model and serial number of the instrument; the date of the calibration; the results of the calibration; and the name of the individual who performed the calibration. We believe that this information will provide adequate documentation of calibrations of instruments used to measure the activity of unsealed byproduct material.

Section 35.2061, Records of Radiation Survey Instrument Calibrations

Issue 1: Is it Necessary to Keep Instrument Calibration Records?

Comment. Commenters suggested that the requirement to retain records of radiation survey instruments be deleted. Some commenters stated that because the current calibration status and expiration date must be displayed on the instrument, they did not see a benefit to radiation safety by maintaining certificates of calibration. Other commenters stated that this section is already covered in 10 CFR 20.2103.

Response. The NRC believes records of calibration should be kept because they can be used to document that the instrument has been calibrated. This is particularly important when the calibration sticker is unreadable, missing, or in error or when an instrument that was used in a required survey cannot be located. Section 20.2103 requires that licensees maintain records of calibrations but it does not provide specific recordkeeping requirements. Therefore, this section is needed to provide medical use licensees with specific information on what items must be maintained in this record.

Issue 2: Were There Any Other Changes Made In This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended § 35.2061 to delete the requirements to include the description of the calibration procedure and the source used in calibrating the meter; the certified exposure rates from the source; the rates indicated by the instrument being calibrated; and the correction factors deduced from the calibration data. These changes are consistent with the revisions made to § 35.61. In the final rule, the licensee is required to record the model and serial number of the instrument; the date of the calibration; the results of the calibration; and the name of the individual who performed the calibration. We believe this information will provide adequate documentation of calibrations of radiation survey instruments.

Section 35.2063, Records of Dosages of Unsealed Byproduct Material for Medical Use

Issue 1: Are Records of Administered Dosages of Unsealed Byproduct Material Needed?

Comment. Commenters did not believe this recordkeeping section was needed because prescribing and dispensing records are required by state medical and pharmacy laws. Other commenters did not believe that the recordkeeping requirements should apply to byproduct material administered under §§ 35.100 and 35.200.

Response. The NRC believes that it is important to keep records of the dosages administered. These records are needed to document that the byproduct material was administered to a patient or human research subject in accordance with the written directive and to document the amount of byproduct material that was administered. However, if a licensee keeps the same records to comply with other requirements, the licensee need not retain duplicate records.

Issue 2: Should the Expiration Date of a Radioactive Drug Be Deleted From the Regulations?

Comment. A commenter indicated that the current requirement in § 35.53 to record the expiration date of a radioactive drug should not be deleted from the regulations. The commenter believed the expiration date is important because it can be used, for example, to establish time limits on sterility, dosage, and effectiveness of tagging. The commenter also believed the paperwork burden for including the expiration date is minimal.

Response. The NRC agrees that the expiration date of a radioactive drug is important. However, we believe that licensees have to comply with other regulations governing the use of drugs that include noting the expiration date because it is related to stability and sterility. Therefore, we do not believe that it is necessary to have a requirement in Part 35 for licensees to record the expiration date of a radioactive drug.

Issue 3: Should the Terms ''Prescribed Dosage'' Be Removed From the Requirement?

Comment. A commenter asked that the term ''prescribed dosage'' be deleted from § 35.2063 because there is no requirement for the AU to prescribe the dosage and, in the case of therapeutic administrations, only a written directive is needed.

Response. The NRC has not deleted the term ''prescribed dosage.'' The term is defined in § 35.2. In Part 35, only an AU may direct the administration of sealed or unsealed byproduct material for medical use.

Issue 4: Were There Any Other Changes Made In This Section Between the Proposed and Final Rules?

Response. Yes. The NRC restructured § 35.2063 to match the format used in other recordkeeping sections. We also deleted the requirements for the record to include the radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical and its lot number. These items were deleted to make the rule less prescriptive. The final rule requires that the licensee record the radiopharmaceutical; patient or human research subject's name, or

identification number, if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi); the date and time of the dosage determination; and the name of the individual who determined the dosage. This information will provide adequate documentation of dosage administrations.

Section 35.2067, Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources

Issue 1: Why Should Licensees Maintain Records of Negative Leak Tests?

Comment. A commenter agreed with retention of positive leak test records, but not with the requirement to maintain records of negative tests.

Response. The rule requires records of all leak tests required by § 35.67(b) to show that leak tests were performed. The NRC changed the final rule to require records of the test results, but a licensee has flexibility in how it records the test results. For negative leak tests, a licensee may simply document that the measured activity is ''negative.''

Issue 2: Should This Section Make a Reference to § 35.2406, Records of Brachytherapy Source Inventory?

Comment. A commenter asked that we add a reference which states that additional brachytherapy records may be required by § 35.2406.

Response. The NRC does not believe this reference is needed. We have tried to eliminate redundancy and cross referencing in the rule unless it is needed to make the rule more understandable.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also deleted the requirements to record the measured activity of each test sample and a description of the method used to measure each test sample in the record. These items were deleted to make the rule less prescriptive.

Section 35.2070, Records of Surveys for Ambient Radiation Exposure Rate

Issue 1: Are Contamination Surveys Included in This Section?

Comment. A commenter indicated that the requirement for records of removable contamination should be deleted because § 35.70 does not require removable contamination surveys.

Response. The commenter is correct. The NRC deleted the requirement for the licensee to record removable contamination in each area (expressed in disintegrations per minute per 100 square centimeters) and the instrument used to analyze the samples. However, the licensee must maintain records to show compliance with ALARA.

Issue 2: Are the Requirements in This Section Already Covered by § 20.2103, Records of Surveys?

Comment. Commenters did not believe this section was needed because radiation surveys are addressed in § 20.2103.

Response. 10 CFR Part 20 contains general provisions on records. Section 20.2103 requires that licensees maintain records of surveys, but it does not provide specific recordkeeping requirements. This section is needed to specify what Part 35 licensees must document in the record required by this section.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC deleted the requirements to record a plan of each area surveyed; the trigger level established for each area; and the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. These items were deleted to make the rule less prescriptive. The final rule requires the licensee to record the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the individual who performed the survey.

Section 35.2075, Records of the Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material

Issue 1: Should Paragraph (b) of This Section That Requires That a Record Be Kept That Instructions Were Provided to a Breast-Feeding Woman Be Deleted?

Comment. A commenter stated that the requirements in paragraph (b) [proposed paragraph (c)] are intrusive into medical practice. The commenter believed that instructions should be left to the physician's judgment.

Response. The NRC did not make any changes in paragraph (b) of the proposed rule which requires licensees to keep a record that instructions, including written instructions, were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem). This requirement is also in the current Part 35. We believe that providing written instructions to patients or human research subjects is necessary because they may not remember all the oral instructions. In addition, written instructions provide needed information to other family members or individuals who are caring for the patient or human research subject.

The requirement for a licensee to retain a record to demonstrate that instructions were provided to a breast-feeding female is more risk-informed. These records are associated with higher risk administrations of radiopharmaceuticals, e.g., therapeutic administrations of iodine-131.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC corrected paragraph (a) of this section because it inadvertently required that licensees maintain records of all releases. This recordkeeping requirement was more restrictive than the current rule. We modified the rule to require records of the release of individuals only when the total effective dose equivalent is calculated by using the retained activity rather than the administered activity; using an occupancy factor less than 0.25 at 1 meter (3.3 feet); using the biological or effective half-life; or considering the shielding by tissue. We also amended paragraph (c) to specify that the records required by both paragraphs (a) and (b) of this section must be maintained for 3 years.

Section 35.2080, Records of Mobile Medical Services

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also deleted the requirement to record a plan of each area surveyed and the measured dose rate at several points in each area of use expressed in millirem per hour. These items were deleted to make the rule less prescriptive. The final rule requires the licensee to record the date of the survey; the results of the survey; the instrument used to make the survey; and the name of the individual who performed the survey. In addition, we clarified that the letter that permits the use of byproduct material must delineate the authority and responsibility of the licensee and the client.

Section 35.2092, Records of Decay-in-Storage

Issue 1: Are the Requirements in This Section Already Covered by § 20.2103, Records of Surveys?

Comment. Commenters did not believe this section was needed because radiation surveys are addressed in § 20.2103.

Response. 10 CFR Part 20 contains general provisions on records. It does not provide specific recordkeeping requirements for disposal of waste through decay-in-storage. Section 35.2092 is needed to specify what Part 35 licensees must document in the records required by § 35.92.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the first sentence to replace the term ''made in accordance with'' with the phrase ''as required by.'' We believe this makes the sentence more readable. We also deleted the requirement to document the name of the radionuclide that was disposed. We do not believe it is necessary for the licensee to document what material was disposed of because § 35.92 no longer requires that the material be held for 10 half-lives. However, this does not preclude the licensee from including this information in the record.

We also amended the requirement so that the record includes the name of the individual who performed the survey, rather than the name of the individual who performed the disposal. We believe that it is important to have a record of the individual who actually surveyed the material and determined that it could be disposed of without regard to its radioactivity.

Section 35.2204, Records of Molybdenum-99 Concentration

Issue 1: Can This Record Be Deleted?

Comment. Commenters suggested that this section, as well as § 35.204, be deleted. They did not believe the rule should require licensees to measure molybdenum-99 concentrations. (See comments on § 35.204.)

Response. The NRC did not delete the requirement for licensees to measure molybdenum-99 concentrations, nor have we deleted the requirement for licensees to maintain a record of the molybdenum-99 concentration tests required by § 35.204. We believe the record is needed to document that the test has been performed and that the results of the test do not exceed the levels specified in § 35.204.

Section 35.2310, Records of Safety Instruction

Issue 1: Is It Necessary To Maintain Records of Safety Instruction Given to Non-Film Badged Workers?

Comment. According to commenters, it is excessive to require licensees to maintain records of training given to non-film badged allied health care workers, who receive instruction in accordance with §§ 35.310, 35.410 or 35.610.

Response. Records of all individuals receiving safety instruction in accordance with §§ 35.310, 35.410 or 35.610 are needed to document that the instruction was provided by the licensee. The NRC believes it is important that the personnel caring for patients or human research subjects who have received radiopharmaceutical therapy (and cannot be released in accordance with § 35.75) receive instruction in limiting radiation exposure to the public or workers and what actions should be taken in the case of a medical emergency or death.

Issue 4: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The title of this section was changed to correspond to the title of § 35.310, Safety instruction. That section includes the requirement for licensees to retain a record of individuals receiving safety instruction.

Section 35.2404, Records of Surveys After Source Implant and Removal

Issue 1: Is It Necessary To Maintain Records of Negative Surveys? Also, Can the Record Retention Requirement Be Changed from 3 Years to 1 Year?

Comment. Some commenters felt that maintenance of negative surveys for 3 years was excessive and suggested that the survey record include only an indication of the survey being performed and the results of any positive surveys. These same commenters also suggested that the record need only be kept for 1 year.

Response. The NRC simplified the recordkeeping requirements in this section by deleting the requirement to record the location of the survey and the patient identifier. These items were deleted to make the rule less prescriptive. We added a requirement to record ''the results of the survey'' because we do not believe that a requirement to record the results of the survey is excessive, even if the results are that all sources are accounted for. We have also retained the 3-year recordkeeping period to be consistent with the 3-year inspection period for most medical use licensees.

Issue 2: Could the Recordkeeping Requirements of This Section Be Less Prescriptive, Consistent With Providing More Flexibility in Running a Radiation Protection Program?

Comment. A commenter suggested that the contents of the record for radiation surveys be deleted, consistent with providing the licensee flexibility in developing, maintaining, and implementing its radiation protection program. If this cannot be done, the commenter suggested that the ''name of the individual'' be changed to ''the identity of the individual.''

Response. The NRC simplified the recordkeeping requirements in this section by deleting the requirement to record the location of the survey and the patient identifier. As discussed in Issue 6 of the general comments on this subpart, we believe that the full name of an individual must appear on a record to better ensure future identification of the individual who performed the survey.

Issue 3: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC changed both the title and regulatory text of this section to accommodate changes made in § 35.404, Surveys after source implant and removal. For example, the term ''radiation'' was struck from the section, recognizing that the survey may not necessarily be a radiation survey. The licensee may also perform a visual survey to locate and account for all sources. Other changes are discussed in the comments on § 35.404.

Section 35.2406, Records of Brachytherapy Source Accountability

Issue 1: Is It Necessary To Retain a Record of Permanent Implant Sources Returned to Storage If All Sources Were Used During the Implant?

Comment. A commenter suggested that, in some permanent implant cases, all of the sources will be utilized. The commenter proposed that the word ''unused'' be added to item (c)(2) immediately before ''sources.''

Response. The NRC changed the regulatory text in this section to require that the record include ''the number and activity of sources not implanted.'' Therefore, if all of the sources were used, the licensee would have to note that all of the sources were implanted and, consequently, none were returned to storage.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The title of this section was changed to correspond to the revised title of § 35.406, Brachytherapy source accountability. That section requires licensees to maintain accountability at all times for all brachytherapy sources in storage or use.

Section 35.2432, Records of Calibration Measurements of Brachytherapy Sources

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The title of this section was changed to correspond to the title of § 35.432, Calibration measurements of brachytherapy sources. That section requires licensees to retain records of calibrations performed before the first medical use of brachytherapy sealed sources. Several changes were also made in this section to accommodate changes made in § 35.432. For example, the proposed rule said that the full calibration measurements must include determination of the output or activity within +/− 5 percent, and the final rule says that a licensee must determine the source output or activity using a dosimetry system that meets the requirements in § 35.630(a). Other changes are discussed in the comments on § 35.432.

Section 35.2433, Records of Decay of Strontium-90 Sources for Ophthalmic Treatments

Issue 1: Were There any Other Changes Made in This Subpart Between the Proposed and Final Rules?

Response. Yes. The NRC added this section to correspond with the new § 35.433, Decay of strontium-90 sources for ophthalmic treatments. That section includes a requirement that a record be made of the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. For additional information, see the discussion for § 35.433.

Section 35.2605, Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also added the word ''adjustment'' to the title and text of this section to conform them with the regulatory text. In addition, the phrase ''remote afterloader unit, teletherapy unit, or gamma stereotactic unit'' was added. This list of units was added because Subpart H in the final rule includes requirements for these types of devices, in addition to the requirements for teletherapy units which are in the current Part 35.

Section 35.2610, Records of Safety Procedures

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. This section was added to the final rule. We explicitly state in this section that the procedures required in §§ 35.610 (a)(4) and (d)(2) must be retained until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51 for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2630, Records of Dosimetry Equipment Used With Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Issue 1: Can the Record Retention Period for This Section Be Changed From ''for the Duration of the License'' to 3 Years?

Comment. A commenter suggested that the record retention period could be changed to ''3 years after the last calibration.''

Response. The NRC has not changed the record retention period in this section. The dosimetry equipment calibrations, intercomparisons, and comparisons performed to show compliance with § 35.630 are necessary to document that the correct radiation dose is delivered to the patient or human research subject. If there is a future question about whether the correct radiation dose was delivered to a patient or human research subject, we believe that these records should be available to document that calibration of the therapy unit has been made with properly calibrated instruments.

Issue 2: Were There Any Other Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more clearly what type of records are required by this section.

We also amended paragraph (b)(2) to require that licensees include the manufacturer's name for the instruments that are calibrated, intercompared, or compared in accordance with § 35.630. This change is consistent with requirements in other sections to include the manufacturer's name of other types of equipment.

Section 35.2632, Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Changes were made in this section to incorporate the requirements that were in the proposed §§ 35.2633 and 35.2635, which were deleted. Section 35.2632 in the final rule includes the recordkeeping requirements for full calibrations of teletherapy, remote afterloader, and gamma stereotactic radiosurgery units. Licensees can refer to this section for all of the recordkeeping requirements for full calibrations of the therapy units covered by Subpart H.

Section 35.2633, Records of Remote Afterloader Full Calibrations

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. This section was deleted in the final rule because the requirements were moved to § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. This change has been made so that all of the recordkeeping requirements for full calibrations of therapy units in Subpart H would be in one place for easier reference for licensees.

Section 35.2635, Records of Gamma Stereotactic Radiosurgery Unit Full Calibrations

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. This section was deleted in the final rule because the requirements were moved to § 35.2632, Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. This

change has been made so that all of the recordkeeping requirements for full calibrations of the therapy units covered by Subpart H would be in one place for easier reference for licensees.

Section 35.2642, Records of Periodic Spot-Checks for Teletherapy Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Paragraph (c) was added to the final rule. We explicitly state in this section that the procedures required in § 35.642 (b) must be retained until the licensee no longer possesses the teletherapy unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51(b) for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2643, Records of Periodic Spot-Checks for Remote Afterloader Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Several changes were made to accommodate changes made in § 35.643.

Paragraph (c) was added to the final rule. We explicitly state in this section that the procedures required in § 35.643 (b) must be retained until the licensee no longer possesses the remote afterloader unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51(b) for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2645, Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Several changes were made to accommodate changes made in § 35.645. These changes are discussed in the comments on § 35.645.

Paragraph (c) was added to the final rule. We explicitly state in this section that the procedures required in § 35.645 (b) must be retained until the licensee no longer possesses the gamma stereotactic radiosurgery unit. Without this explicit statement, the licensees would have to reference the general recordkeeping provisions in § 30.51(b) for the record retention period and therefore, would have had to retain the procedures for the duration of the license.

Section 35.2647, Records of Additional Technical Requirements for Mobile Remote Afterloader Units

Issue 1: Were There Any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. Other changes are discussed in the comments on § 35.647.

Section 35.2652, Records of Surveys of Therapeutic Treatment Units

Issue: Can the Record Retention Period Be Changed to 3 Years, Instead of ''for the Duration of Use of the Unit?

Comment. A commenter suggested that the record retention period could be changed to 3 years.

Response. The NRC has not changed the record retention period in this section. The surveys performed to show compliance with § 35.652 are necessary to ensure that the source/device radiation level limits stated in the SSDR are not exceeded. We believe that these surveys should be retained for the duration of use of the device because of the potential radiation risks associated with these devices.

Subpart M—Reports

Issue 1: Should All the Reporting Requirements Be Grouped Into One Subpart or Should They Be Incorporated Into the Section Requiring the Report?

Comment. Commenters provided diverse responses to the Commission's question on whether all of the reporting requirements should be grouped into one subpart, or whether they should be incorporated into the individual sections requiring the reports. Commenters favored having all of the reporting requirements in one subpart because this format provides for easy reference, simplifies licensing, and assists licensees in determining their reporting requirements, which makes it easier to maintain compliance. Other commenters favored having the reporting requirements in the individual sections because this format is more orderly and informative. They find the similar separation of the actual reporting requirements and the requirements for what needs to be in the reports in Part 20 to be confusing. A number of individuals have misinterpreted sections of Part 20 simply because of the separation. Several commenters preferred a balanced approach where the reporting requirements would be in the individual sections and all of the requirements summarized in a separate subpart.

Response. After reviewing all of the comments responding to this question, the NRC concluded that having all of the reporting requirements in one subpart makes it easier for licensees to reference those requirements. However, the final rule is consistent with the ''balanced approach'' because each section in the final rule that is associated with a reporting requirement includes a cross-reference to the specific reporting requirements in Subpart M.

Section 35.3045, Report and Notification of a Medical Event

Issue 1: Do Stakeholders Think That the Term ''Medical Event'' is an Improvement Over the Use of the Term ''Misadministration'' in the Current Part 35?

Comment. Commenters supported the use of the term ''medical event.'' One commenter agreed with the change, but could see no reason for ''candy coating'' the term ''misadministration.''

Response. The NRC used the term ''medical event'' in the final rule because some believe the term ''misadministration'' has a negative connotation that implies negligence on the part of the physician or other hospital workers. The term ''medical event'' more correctly and simply conveys that the byproduct material or radiation from byproduct material was not administered as directed by the AU.

Issue 2: Are the Reporting Requirements for Medical Events Necessary?

Comment. Several commenters said that there was no need for the requirements in this section. Events that result from poor radiation protection practices are covered in the primary regulations for the use of radioactive material, e.g., inadequate survey of a patient following an HDR treatment. If such problem areas in licensees' programs are brought to their attention, licensees can correct the problems before they result in medical events.

Other commenters expressed concern that the overall wording in this section is subject to a great deal of interpretation and debate over whether specific actions are appropriate for a particular patient and whether an event is a reportable medical event. Therefore, the NRC should develop more specific language describing a medical event in order to avoid intrusion into medical judgments. It should be made clear that medical events are major deviations from a planned treatment that have or could have significant effects on the patient. These effects include either a

reduction in the possibility of tumor control or an increase in the possibility of complications. In addition, licensees should be able to appeal to medical experts if NRC staff determines that an incident is a reportable medical event.

Response. The NRC believes that the reporting and notification requirements in this section are necessary so that the NRC is aware of events that trigger the thresholds for medical events to determine what actions, if any, need to be taken to prevent recurrence; so that other licensees can be made aware of generic problems that result in medical events; and so that patients can make timely decisions regarding remedial and prospective health care. The requirements throughout Part 35 are more specific for medical use than the general requirements for the use of radioactive material in the other parts, e.g., Part 20 requirements.

During the development of the final rule, we revisited the proposed wording of all sections, including § 35.3045, to see if we could clarify the regulatory text to avoid future misinterpretations and debates about the meaning of the regulatory text. This type of clarifying change has been made to exclude reporting medical events that are due to ''patient intervention.''

Issue 3: Are the Threshold Dose Levels for Reporting Medical Events Set at Appropriate Levels?

Comment. Some commenters said that the reporting levels for medical events in the proposed § 35.3045(a)(1) cannot be justified on the basis of any real risk to either patients or the public. Reporting at these levels implies that these events result in harm to the patient, when they often result in no effect on the patient. Therefore, this is an example of a low risk requirement that the 1997 NAS–IOM Report (Radiation in Medicine: A Need for Regulatory Reform, Institute of Medicine, National Academy Press, Washington, DC, 1997) recommended be deleted. In addition, inherent risks do not justify intrusion by NRC into professional activities and the doctor-patient relationship.

Commenters said that the action level criteria for the total dose delivered from brachytherapy procedures or gamma stereotactic radiosurgery procedures should be revised from the prescribed dose to a level at which harm to patients has been demonstrated. Another commenter questioned why the threshold was not similar to FDA's requirements for reporting morbidity and mortality.

One commenter said that the reporting thresholds of 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue were reasonable levels because they are ''reasonably significant radiation exposures.'' Five rem is the annual limit for a radiation worker, and 50 rem to an organ is the level when one might start seeing organ effects. For example, 50 rem to the testicles will result in a decreased sperm count.

Response. The NRC made no change in the proposed threshold reporting levels for medical events. These reporting levels correspond to the annual occupational dose limits in Part 20 and the level for reporting overexposures of workers to NRC. We believe that applying these same thresholds to reporting exposures to patients is reasonable.

The NRC uses the information from the reports of medical events that exceed the dose thresholds to reduce the likelihood of other medical events. For example, information from a report may indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation from byproduct material is administered as directed by the AU or may indicate a generic issue that should be reported to other licensees.

Issue 4: Should Licensees Be Required to Report Events In Which the Administration of Byproduct Material or Radiation From Byproduct Material Results in a Total Dose That Differs From the Prescribed Dose by 20 Percent or More?

Comment. Commenters said that the 20 percent difference is arbitrary, and that exceeding this limit presents little or no risk to the patient. The limit should be examined and justified. Recommendations ranged from the limit should be 100 percent, to maybe there should not be a limit and the physician can decide when to report harm to a patient, to it is inappropriate to have a single criterion for all procedures.

Commenters believe that the 20 percent limit is reasonable for external beam therapy and unsealed therapeutic radiopharmaceuticals, but that it is too restrictive for brachytherapy, gamma stereotactic radiosurgery, and unsealed diagnostic dosages. Commenters said that they were aware of clinical data that supported the 20 percent level for external beam therapy. However, they were unaware of any brachytherapy or gamma stereotactic radiosurgery data demonstrating that a 20 percent difference between the prescribed dose and delivered dose would result in harm to the patient. In addition, a few millimeters in brachytherapy can make a tremendous difference in the dose. Some provision should be made to exempt brachytherapy, or to change the 20 percent limit up to 100–120 percent.

Several commenters questioned the applicability of the 20 percent limit to uses of unsealed byproduct material. Exceeding a radiotherapy dosage by 20 percent may be significant, but reporting an administration of a diagnostic dosage that exceeds the prescribed dosage by 20 percent is overregulation.

Response. The NRC has retained the 20 percent difference that is in the current rule. According to the Statements of Consideration for the Quality Management Program and Misadministrations rulemaking (56 FR 34104; July 25, 1991), a 20 percent difference between the prescribed dose and the total dose delivered is required to be reported because it could possibly indicate a deficiency in the licensee's program, not because it necessarily indicates a significant risk to the patient. We agree with this rationale and see no reason to change the threshold.

Licensees should note that they do not have to report an event in which the total dose or dosage delivered differs from the prescribed dose or dosage by 20 percent or more unless the dose also differs from the prescribed dose or from the dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

The NRC uses the information from the reports of medical events where the administration of byproduct material or radiation from byproduct material results in a total dose that differs from the prescribed dose by 20 percent or more to reduce the likelihood of other medical events. For example, the difference between the prescribed and administered doses may indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation from byproduct material is administered as directed by the AU.

Issue 5: Does the Proposed Rule Adequately Address Wrong Treatment Site?

Comment. Commenters both agreed and disagreed on whether the proposed rule adequately addressed wrong treatment site. Two commenters said that it was unclear how wrong treatment site will be handled for therapy, especially for brachytherapy where a medical event can occur if the patient moves even a small distance. In addition, commenters questioned how the wrong treatment site criteria will be applied to permanent seed implants that migrate from the prescribed site.

Another comment was that the criteria for a medical event involving the wrong treatment site must be justified. The criteria of a 0.5 Sv (50 rem) tissue/organ dose and difference of 20 percent from the expected dose defined in the written directive are excessively restrictive. Justification can be provided that the percentage deviation could be 100 percent. At a minimum, radiobiological justification can be made for 1 Sv (100 rem) as a significant threshold. The FDA uses this threshold criteria for evaluating lengthy fluoroscopy studies that could result in skin injury.

Response. In § 35.3045(a)(3) of the proposed rule, the NRC attempted to define more clearly when exposure of a wrong treatment site is considered a medical event by including both a 0.5 Sv (50 rem) tissue/organ dose limit and a 20 percent deviation from the expected dose defined in the written directive. We believe that the proposed 0.5 Sv (50 rem) tissue/organ dose limit should be retained, but the allowable deviation from the dose in the written directive should be increased to 50 percent. Therefore, we amended paragraph (a)(3) of this section in the final rule to read ''50 percent of the dose expected * * *'' We believe that this change allows for some variation in doses to the wrong treatment site during administrations of radiation from byproduct material, and requires licensees to only report significant doses to the wrong treatment site due to the movement of the patient or source, e.g., during brachytherapy treatments. In addition, we added a statement that is in the current rule, which was inadvertently not included in the proposed rule, that excludes permanent implants of seeds that were implanted in the correct site but migrated outside the treatment site.

Issue 6: Does the Proposed Rule Adequately Address Patient Intervention?

Comments. The NRC received a range of responses to the Commission's question on whether the proposed rule adequately addressed patient intervention, i.e., actions by the patient such as dislodging or removing treatment devices or prematurely terminating treatment. Several commenters said that this issue was adequately addressed in the rule. Other commenters said that any patient intervention should not result in a medical event. One commenter said that an exemption should be provided to the licensee when the cause of a medical event is patient intervention.

A number of commenters said that the phrase in the proposed rule ''that could have been prevented by the licensee'' was ambiguous and subjective, and should be deleted because it would result in varying interpretations between NRC and licensees. In addition, decisions on what are considered ''reasonable medical practices'' for patient control infringe on the practice of medicine and should be left to the physician's professional judgment. Therefore, this requirement is in violation of Statement 2 of the proposed revision of the Medical Policy Statement: NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

Response. As part of the medical use rulemaking, the Commission is codifying a common-sense approach to the reporting requirements for medical events that excludes incidents involving patient intervention. In the proposed rule, the phrase ''that could not have been reasonably prevented by the licensee'' was added to § 35.3045(a) in an attempt to avoid further expenditure of resources by licensees and NRC in trying to determine what constitutes patient intervention, which is not specifically addressed in the current rule. The issue has involved whether or not a licensee did everything it should to prevent patient intervention during a treatment that resulted in a medical event. Following our evaluation of the comments on patient intervention, the NRC deleted the proposed phrase from § 35.3045(a) because it did not seem to clarify when an event caused by patient intervention must be reported to NRC as a medical event.

In the final § 35.3045(b), we addressed the issue of when an event caused by patient intervention must be reported to NRC as a medical event. In addition, we added a definition of patient intervention to § 35.2. As defined, patient intervention means ''actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.'' We believe licensees should only be required to report serious medical events due to patient intervention. Paragraph (b) of this section in the final rule requires licensees to report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. As a result of the significantly higher threshold, the NRC will only receive reports involving patient intervention for events with serious consequences, e.g., unintentional permanent functional damage.

This reporting requirement should result in decreased regulatory burden on licensees because in most situations where patients intervene in their treatment, either voluntarily or involuntarily, there is no permanent functional damage. Therefore, the revised reporting requirement should significantly reduce the resources expended by the NRC and licensees in debating what are considered reasonable medical practices for patient control because the NRC will no longer require most of the reports it currently receives involving patient intervention. In addition, it should avoid intrusion into medical judgments by the NRC because the decision on whether the administration resulted in permanent functional damage to an organ or a physiological system is to be determined by a physician.

Issue 7: Why Do Licensees Need To Notify the NRC By Telephone No Later Than the Next Calendar Day After Discovery of a Medical Event?

Comment. Two commenters questioned the need for licensees to notify the NRC no later than the next calendar day after discovery of a medical event because this requirement implies that these events are harmful or hazardous. There are some medical events with serious consequences that should be reported right away but there is no benefit in reporting events with no medical significance so promptly.

Response. According to the Statements of Consideration for the Quality Management Program and Misadministration final rule [56 FR 34104; July 25, 1991], misadministrations (medical events) warrant telephone notification of the NRC no later than the next calendar day because these events require that a threshold of either 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) dose equivalent be exceeded. The early telephone notification allows the NRC to promptly take any necessary actions based on the circumstances, e.g., dispatch an inspector or medical consultant or notify other licensees of potential generic problems. The NRC continues to believe that licensees should promptly notify the NRC of medical events that trigger these thresholds because the circumstances of the medical events need to be evaluated as soon as possible to determine if any

immediate follow-up or corrective actions are necessary.

All medical events may not be associated with serious consequences. However, we believe that a requirement that allows for different reporting periods, depending on the initial assessment of the event, would lead to differing interpretations and confusion as to whether the magnitude of the event requires notification of the NRC no later than the next calendar day. In addition, there may be a medical event where the seriousness of the consequences would not be immediately apparent and which, therefore, would not be reported.

Issue 8: Should Licensees Be Required To Notify the Individual (Affected By the Medical Event) About a Medical Event?

Comment. The NRC received a range of comments on the requirement in § 35.3045(e) to notify the individual affected by the medical event. These ranged from the licensee should always notify the patient or guardian to this requirement should be deleted.

Some commenters suggested modification of the requirement. For example, a licensee should be allowed not to notify an individual if the rationale for withholding the information is noted in the written report to the NRC. Other suggestions were that notification of the patient should not be required unless the medical event results in a detrimental effect to the patient, or it is necessary to ensure patient safety.

Other commenters said that the requirement should depend on the risk of the procedure. In cases of diagnostic and low-risk therapeutic procedures, notification should not be mandatory. For high-risk therapeutic applications, a patient should only be notified if an adverse outcome is probable and only if the patient's mental state would not be adversely affected.

Commenters provided a number of reasons why they felt that this requirement should be deleted: it overlaps with existing medical practice standards; it intrudes into the practice of medicine; it interferes with the physician-patient relationship; there are no data that patients are not being notified; it presents the appearance of much greater harm than there may actually be; there is no precedent in other areas of medicine; and it is in contradiction to NRC's Medical Policy Statement.

Response. The NRC retained the proposed requirements for notifying individuals following a medical event in the final rule. As stated in the proposed rule (63 FR 43516; August 13, 1998), this position reaffirms statements made by the Commission during the misadministration rulemaking, that patient notification '' * * * recognizes the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector'' [''Human Uses of Byproduct Material, Misadministration Reporting Requirements,'' (43 FR 2927; May 7, 1978)]. We continue to believe that patient notification enables patients, in consultation with their personal physicians, to make timely decisions regarding any remedial and prospective medical care. This approach also codifies existing medical ethical standards obligating physicians to provide complete and accurate information to their patients.

This approach is consistent with aspects of another Federal patient notification requirement specifically in ''The Mammography Quality Standards Reauthorization Act of 1998,'' Pub. L. 105–248, under which notification of a patient may be required for certain events (e.g., when a patient has received mammography from a facility whose quality is found to be ''so inconsistent with quality standards as to present a risk to individual or public health''). [42 U.S.C. 263b(h)(2)(1999)]. By statute, as well as FDA regulations, a summary of the written report of the patient's mammography results must be sent directly to the patient if the patient's physician is not available or if there is no such physician. [42 U.S.C. 263b(f)(1)(G)(ii)(III); 21 CFR 900.12(e)(1)(2)(ii)(a) and (iii) (1999).]

Issue 9: Should Licensees Be Required To Notify the Referring Physician About a Medical Event?

Comment. Several commenters disagreed with the need for a regulation requiring licensees to notify referring physicians about a medical event. Nuclear medicine physicians and referring physicians have a professional relationship that would be negatively impacted if the nuclear medicine physician provided inaccurate information or withheld information from the referring physician. Therefore, the NRC does not need to mandate notification of the referring physician.

Response. It is important that a referring physician is aware of medical events involving individuals. The referring physician knows the individual and his or her medical history and is likely to be in the best position to make a decision about whether informing the individual about the medical event would be harmful. That physician may also need to evaluate any follow-up actions relative to the individual's overall health history. Although notification of referring physicians may represent the ''standard of care,'' that practice may not be uniformly followed. Therefore, the NRC retained the current requirement for a licensee to notify the referring physician about a medical event. The final rule includes a requirement that licensees annotate a copy of their report to the NRC about the medical event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. We believe that it is important for the referring physician to have all the available documentation about the medical event to support any decision about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record is based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. Consistency, where possible, between the requirements in Subparts L and M will simplify compliance with the recordkeeping and reporting requirements.

The issue of notifying the referring physician was addressed in the Statements of Consideration for the 1995 rulemaking that amended the medical misadministration requirements (''Medical Misadministration of Radiation and Radioactive Material,'' 60 FR 48623; September 20, 1995). The Commission noted that ''If a misadministration occurs because the material was administered to the wrong individual, there may be no referring physician. If there is no referring physician, the licensee is relieved of the responsibility of notifying the referring physician, but must comply with all other requirements of § 35.33.''

Issue 10: Why Is There a Requirement for a Licensee To Provide a Written Report to the Individual Affected by a Medical Event?

Comment. The NRC received several comments on the need for a licensee to provide a written report to the individual affected by a medical event. Commenters were concerned that providing a written report to the individual may lead to a misunderstanding of the consequences for the patient (i.e., the individual may be unduly alarmed that a report had to be submitted to NRC) and jeopardize the individual's confidence in the ability of the physician providing medical care. Another commenter noted that there is no precedent for providing a written

report to a patient about a misadministration of other diagnostic agents.

Response. The NRC deleted the current requirement to furnish an individual affected by a medical event with a written report. Instead, in the final rule licensees are required to inform the individual, or responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are required to provide such a written description to the individual, if requested. We believe that a written report would be especially useful to an individual who needs to make decisions about any follow-up medical care, and provides the individual a permanent record to refer to for information about the event.

Issue 11: What Other Changes Were Made as a Result of Comments?

Comment. It is not clear whether the thresholds in paragraph (a)(1) and either (a)(1)(i) or (ii) need to occur simultaneously for the event to be reported.

Response. The NRC made editorial changes in the text of paragraph (a) to make it clearer that an event is only classified as a reportable medical event if both the threshold in paragraph (a)(1) and the threshold for the difference between the total dose and prescribed dose in paragraph (a)(1)(i) or the difference between the total dosage and prescribed dosage in paragraph (a)(1)(ii) or the difference between the fractionated dose delivered and the prescribed dose in paragraph (a)(1)(iii) have been exceeded.

Comment. The word ''of'' is missing between ''20 percent'' (50 percent in the final rule) and ''the dose expected'' in paragraph (a)(3) of this section that addresses the threshold for determining when a dose to a ''wrong treatment site'' is a reportable medical event.

Response. The text of paragraph (a)(3) of this section has been corrected to read ''50 percent of the dose expected from the administration defined in a written directive.''

Comment. Paragraphs (c)(1)(vi) and (vii) could be combined into one paragraph because they both address actions or improvements that have been taken, or are planned, to prevent recurrence of a medical event.

Response. We combined the requirements in the proposed paragraphs into paragraph (d)(1)(vi) in the final rule.

Issue 12: Were There Any Other Changes Made in This Section Between the Proposed and Final Rule?

Response. Yes. The NRC amended the title of this section to state more correctly that this section includes both reporting and notification requirements for medical events.

The phrase ''results from intervention by a patient or human research subject'' in paragraph (a) of the proposed rule was deleted and replaced by ''an event that results from patient intervention'' in the final rule. We made this change because the definition of patient intervention in § 35.2 includes actions by either a patient or human research subject, so paragraph (a) of the proposed rule contained duplicative language.

We added the phrase ''administration of byproduct material or radiation from byproduct material'' in paragraph (a) of the final rule because the requirements in Part 35 are limited to the medical use of byproduct material.

Paragraph (a)(1) was clarified to add the phrase ''dose that would have resulted from the prescribed dosage.'' This change was needed to clarify that this provision applies to the medical use of sealed and unsealed byproduct material as evidenced by the reference to ''total dosage'' in paragraph (a)(1)(ii).

Paragraph (a)(1)(i) of the proposed rule that contained the threshold for the difference between the delivered dose or dosage and the prescribed dose or dosage was split into paragraphs (a)(1)(i) and (ii) in the final rule. We made this change to reflect the fact that physicians can prescribe a range of dosages, but not doses, in written directives.

We replaced the word ''pharmaceutical'' in paragraph (a)(2)(i) with ''radioactive drug containing byproduct material'' because the requirements in Part 35 are limited to the medical use of byproduct material.

We amended paragraph (a)(3) to read ''50 percent or more'' (20 percent in the proposed rule) to make it clearer that the dose to a wrong treatment site has to exceed 50 percent or more of the dose expected from the administration defined in the written directive before a licensee is required to report the event to NRC as a medical event.

Paragraphs (d)(1)(v)and (vi) [paragraphs (c)(1)(v) and (vii) of the proposed rule] require that information on the effects of the medical event on the individual who received the administration and on the actions to prevent recurrence be included in the written report to the NRC. We reworded these paragraphs in the final rule to read ''the effect, if any, on the individual;'' and ''what actions, if any, have been taken, or are planned, to prevent recurrence.'' The words ''if any'' and ''are planned'' were added because there might not be any effect or any actions taken at the time the event is reported.

We revised paragraph (d)(1)(vii) [paragraph (c)(1)(viii) in the proposed rule] to require that the written report include a certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not. We made this revision because notifying these individuals is important enough to warrant documentation that the individual(s) was notified. In addition, we believe that it is important that the licensee notify the patient so that he or she can be actively involved in any decision about remedial or prospective health care following the event.

We deleted paragraph (c)(1)(ix) in the proposed rule because the referring physician, and not the licensee, may have notified the individual. Therefore, the licensee may not know what information the referring physician provided to the individual.

We amended paragraph (e) [paragraph (d) of the proposed rule] in the final rule. The words ''when appropriate'' were deleted from the last sentence in paragraph (d) of the proposed rule because the intent was covered by the phrase ''may be made'' in the same sentence.

We added paragraph (g) to the final rule to require that licensees annotate a copy of their report to the NRC about the medical event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the medical event. We believe that it is important for the referring physician to have all the available documentation about the medical event to support any decision about remedial or prospective health care.

Section 35.3047, Report and Notification of a Dose To An Embryo/Fetus or a Nursing Child

Issue 1: Should the Abnormal Occurrence Policy Statement Criteria for Reporting of Unintended Exposures to an Embryo/Fetus or Nursing Child Be Modified?

Comment. Numerous commenters recommended that § 35.3047 be deleted and the Abnormal Occurrence (AO) Criteria be revised to reflect the deletion of this section.

Response. The information required by this section is needed so that NRC can comply with Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93–438, 5848, 42 U.S.C.), as amended, to submit an annual report to

Congress of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, e.g., abnormal occurrences. (The ''Reports Elimination Act,'' Pub. L. 104–66, changed the Abnormal Occurrence (AO) report to a yearly publication.)

The NRC identifies an abnormal occurrence using the revised abnormal occurrence criteria that were published in the **Federal Register** (62 FR 18820; April 17, 1997). Section II of that policy statement defines unintended radiation exposure as ''any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in § 35.2) involving the wrong individual that exceeds the reporting values established in the regulations.'' This section also states that ''All other reported medical misadministrations will be considered for reporting as an Abnormal Occurrence under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values.'' Appendix A, Section I.A.2., ''Abnormal Occurrence Criteria,'' of the policy statement, states that NRC will provide information on ''any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual total effective dose equivalent of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.''

At the present time, the NRC has no regulatory requirements that require licensees to report those types of events. Therefore, the Commission considered two alternatives: revise the current Abnormal Occurrence Criteria to delete the requirement to report this type of event to Congress; or develop a reporting requirement for licensees that would provide the information needed by the Commission to comply with Section 208.

After extensive discussion and consideration of the public comments, we have decided to pursue the second option. We are not convinced that it is inappropriate for the NRC to report this type of event to Congress and that the reporting requirement in § 35.3047 will be overly burdensome or unwarranted. We are also not inclined to further revise the AO criteria because they have recently been revised and limited comments were received on the proposed criteria.

The thresholds for reporting an unintended dose to an embryo/fetus or a nursing child have been raised in the final rule to the reporting levels in Appendix A, Section I.A.2, of the AO policy statement. Licensees are now required to report any unintended dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent and any dose to a nursing child that is either greater than 50 mSv (5 rem) effective dose equivalent or results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. We believe that § 35.3047, as revised in the final rule, provides a balanced resolution of this issue. The regulatory burden on licensees will be substantially less than it would have been under the proposed § 35.3047 because of the higher reporting thresholds in the final rule; and the NRC will receive the information it needs to report to Congress. In addition, because of the more serious consequences associated with these higher thresholds, we believe that the NRC should receive reports of these unintended doses to an embryo/fetus or nursing child.

Issue 2: What Is the Impact of the Proposed Reporting Requirement on Licensee Procedures, Activities, or Medical Practices?

Comment. According to the comments, the biggest impact of the proposed reporting requirement on licensees is associated with the need to determine the pregnancy status of individuals. Commenters had many concerns about NRC's expectations of pregnancy testing, such as delays in emergency scans pending the completion of pregnancy tests; the sensitivity of pregnancy tests; false negative tests in early pregnancy; the age range for pregnancy testing; privacy of minors; patients refusing to pay for pregnancy tests; and the method for calculating conception dates.

Commenters were also concerned about the licensees' responsibilities when they find out later that there was an unintended exposure to a pregnant individual. This can happen if, for example, the patient may not be aware of, or opts to conceal, the fact that she is pregnant. Licensees should not be held responsible for what patients do against medical advice and reporting such incidents will not prevent a recurrence. Unintended exposures may also occur in cases where the AU is not required to examine the patient, consult with the referring physician, or see the patient's chart, e.g., non-iodine diagnostic studies.

Commenters said that the overwhelming majority of nuclear medicine procedures are safe to perform on pregnant women. In fact, they are often the tests of choice for pregnant women because other radiologic procedures frequently involve higher radiation doses. For the few cases in which administration of a pharmaceutical is not recommended (e.g., sodium iodide I–131), pregnancy information is ascertained. They believe that, by default, the proposed requirement will require pregnancy testing on every female of childbearing age. The inaccuracy, costs, etc. of the tests will lead patients to seek alternative, and often less effective, treatments.

Response. The Commission recognizes that the standard of practice for AUs is to assess the pregnancy or nursing status of their patients (reference ACR ''Standard for the Performance of Therapy with Unsealed Radionuclide Sources,'' 1996, and ''Society of Nuclear Medicine General Procedure Guidelines for Imaging with Radionuclides,'' 1997). As a result, we do not believe that it is necessary for the NRC to require a licensee to assess the pregnancy or nursing status of patients before a medical treatment involving byproduct material.

We do believe that it is appropriate to require the licensee to inform the NRC when the licensee learns of an unintended dose to an embryo/fetus or a nursing child that exceeds the thresholds in § 35.3047. The occurrence of such an unintended dose does not necessarily mean that the licensee is in violation of the requirements in Part 35 as long as the licensee reports it and it is not otherwise in violation of NRC regulatory requirements.

However, the NRC acknowledges that, in some cases, the licensee might not be able to prevent the dose to an embryo/fetus or nursing child. For example, there is no way for an AU to prevent administration of an unintended dose to an embryo/fetus if the pregnancy test was negative because it was given very early in the pregnancy.

Issue 3: What Should Be the Reporting Threshold for a Dose to an Embryo/Fetus or a Nursing Child?

Comment. Commenters said that the proposed reporting level of 5 mSv (500 millirem) to an embryo/fetus or a nursing child is not consistent with the Commission's intent of making Part 35 more risk-informed and performance based because it cannot be justified on the basis of risk. This reporting level is also not consistent with the NRC's need to submit an annual report to Congress

on unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety, i.e., abnormal occurrences. One commenter noted that significant biological effects would not be observable at this reporting level in either an embryo/fetus or a nursing child, as demonstrated by the healthy births of children who were exposed to radiopharmaceuticals in utero for the purpose of diagnosing the mothers of these children. The only radiation doses that truly present a significant health and safety issue are those which result in actual non-stochastic effects. Therefore, another commenter suggested that the NRC consider only those medical events which result in actual non-stochastic effects as abnormal occurrences. In addition, one commenter said that there is no similar requirement by agencies regulating diagnostic x-ray machines. Furthermore, the proposed reporting level is going to result in NRC receiving a number of reports of questionable accuracy and utility.

Commenters suggested a range of reporting levels from 1–25 rem dose equivalent. One commenter suggested that the reporting level should be the same as for medical events: 5 rem total effective dose equivalent or 50 rem to an organ or tissue. Another commenter noted that at his institution, genetic counselors do not consider radiation to be a risk until about 15–20 rem to the embryo/fetus. One commenter suggested that licensees report only radiation-induced injuries and deaths from radiopharmaceuticals and radiologic devices that were due to accidents and that were not reportable to the FDA.

A commenter noted that NCRP Report No. 54, ''Medical Radiation Exposure of Pregnant and Potentially Pregnant Women'' (1977), states that the risk to the embryo/fetus is negligible below 5 rad and is only significant when compared to other risks of pregnancy above 15 rad. This is consistent with the recommendations in AAPM Radiation Therapy Task Group No. 36—Fetal Dose from Radiotherapy with Photon Beams, 1995 (AAPM TG–36).

Commenters also noted that the lack of adequate data makes it virtually impossible to accurately calculate radiation doses to an embryo/fetus at various gestational periods from radiopharmaceuticals. They also questioned how the NRC suggests that patients be monitored to ensure that they are complying with instructions about breast feeding if the nursing child could receive a dose in excess of 100 millirem.

Response. Following an evaluation of the comments and further review of published recommendations and literature, the NRC changed the reporting thresholds in § 35.3047 in the final rule. Paragraph (a) requires that a licensee report to the NRC any administration of byproduct material or radiation from byproduct material to a pregnant woman that results in a dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent unless the administration was specifically approved, in advance, by the AU. We emphasize that only unintended exposures must be reported to the NRC. If a licensee knows that an individual is pregnant and makes the decision that it is necessary to proceed with a test involving the administration of byproduct material or radiation from byproduct material, the licensee would not have to report the dose to the pregnant individual as a medical event. Paragraph (b) requires that a licensee report to NRC any administration of byproduct material to a breast-feeding woman that results in a dose to the nursing child that is greater than 50 mSv (5 rem) total effective dose equivalent or a dose that has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. These reporting levels are consistent with the recommendations in NCRP Commentary No. 9, ''Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus or Nursing Child'' (1994). At a reporting threshold of 50 mSv (5 rem), there are no detectable deterministic effects, and the risk of stochastic effects (e.g., cancer) is less than 1 percent. This report concluded that ''setting requirements for action after radiation exposure of the embryo, fetus, or nursing child at some level below an effective dose of 100 mSv (10 rem) to allow for a margin of safety should enable all such incidents with the potential for harm to be dealt with appropriately.''

We believe that the reporting threshold on the final rule is not overly burdensome on licensees. Unintended doses to an embryo/fetus or nursing child exceeding 50 mSv (5 rem) are rarely encountered in the practice of nuclear medicine (refer, for example, to Russell, J.R., et. al, Radiation Absorbed Dose to the Embryo/Fetus from Radiopharmaceuticals, Health Physics 73:756–769;1997).

Issue 4: Should § 35.3047 Include a Requirement for a Licensee To Notify a Pregnant Individual or Mother About an Event That Must Be Reported to the NRC in Accordance With This Section?

Comment. The physician should be able to determine whom to notify. The method and extent of notifying a pregnant individual or mother are solely a matter of the physician's judgment, within the context of the physician-patient relationship. In some cases, the best individual to notify may be the pediatrician (or future pediatrician), which is not an option in the rule. The pediatrician, not the mother's referring physician, will be caring for the infant. The notification requirements in this section are an intrusion into the practice of medicine.

Response. The NRC retained the requirement for notification of the pregnant individual or mother in the final rule. Although notification of the pregnant individual or mother may represent the ''standard of care,'' that practice may not be uniformly followed. We believe that the pregnant individual or mother should be notified so that she can participate in any decisions on follow-up medical care, if necessary.

Issue 5: Is there a Better Term Than ''Responsible Relative or Guardian'' That Could be Applied to Those Situations Where the Mother is Not Notified, e.g., in the Referring Physician's Medical Judgment Telling the Mother Would Be Harmful; the Mother Is a Minor; or the Mother Is Not Competent To Make Decisions Regarding Medical Care?

Comment. Several comments were received in response to this question, which was published in the proposed rule. Some commenters said that the term ''responsible relative or guardian'' itself was sufficient, and recommended no alternative wording. The term ''guardian'' appears to be very clear because the only comment on guardian said that it does not need to be fixed.

The NRC also received several comments on the interpretation of ''responsible relative.'' Several commenters hoped that ''responsible'' is not used as a substitute for ''legal.'' The term ''responsible'' should allow for notification of someone who cares for the minor but who is neither a blood relative nor a legal guardian. Not telling the mother only because she is a minor is not a responsible rule and is inappropriate. The medical community and the laws of each state determine if a mother is allowed information that may affect her child if she is a minor. The other two situations, it would be

harmful to the mother or the mother is not competent, should cover when notification of the responsible relative or guardian is necessary. Another commenter said that for an adult, what is really meant by notifying the ''responsible relative'' is notifying the relative or individual who has medical power of attorney.

Response. The final rule retains the current phrase ''responsible relative or guardian'' because the NRC did not receive any suggested term that better captures the intent of this requirement, which is that someone be told in those situations where the mother is not notified. We believe this terminology could include an individual who has medical power of attorney. However, it would be unduly restrictive to limit the individual to be notified, in lieu of the patient, to an individual with medical power of attorney. A physician's decision on whom to notify is based on many factors, including the Code of Medical Ethics of the American Medical Association and state laws that govern the release of a patient's medical information to another individual.

To assist with the interpretation of the current notification requirements in the misadministration rule, the Commission had previously provided the examples used in the question of when it expects that a ''responsible relative or guardian,'' rather than the patient, would be notified about a misadministration. These were provided only as examples, and are not part of the actual regulatory text, e.g., we did not intend by the examples that a mother should not necessarily be notified if she is a minor. We believe that the referring physician should have the discretion to either inform the mother or to determine that, based on medical judgment, telling her would be harmful, in which case the mother's or child's responsible relative should be notified.

Issue 6: Why Do Licensees Need To Notify the NRC, by Telephone, Within 5 Days and in Writing no Later Than 15 Days After Discovery of a Dose to an Embryo/Fetus or Nursing Child that Requires a Report Under This Section?

Comment. Commenters questioned the need to notify NRC by telephone within 5 days and in writing no later than 15 days after discovery of a dose to an embryo/fetus or nursing child that requires a report under this section. These reporting requirements give the perception that there is much greater harm than there actually is. One commenter said that the licensee should only have to report in writing to the Regional Office within 30 days after discovery of the dose. The other commenter said that notification of the NRC should be changed from 5 days to 15 days after discovery of the event, or at least changed to 5 working days so there is ample time over a holiday period. The additional time is needed for the licensee to assure the validity of the information in the report.

Response. The final rule contains a significantly higher reporting threshold than the proposed rule for reporting an unintended dose to a nursing child or an embryo/fetus as a result of the unintentional administration of byproduct material or radiation from byproduct material. Licensees are now required to report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent and any dose to a nursing child that is either greater than 50 mSv (5 rem) effective dose equivalent or results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. More serious consequences are associated with these higher thresholds. Therefore, the reporting requirement in the proposed rule to notify the NRC within 5 days after discovery of the unintended dose has been revised to require notification of the NRC no later than the next calendar day. Early telephone notification will allow the NRC to promptly take any necessary actions based on the circumstances, e.g., dispatch a medical consultant. Prompt notification of events that trigger these thresholds is important because the circumstances of the medical event may need to be reviewed as soon as possible to determine if any follow-up actions are necessary.

The reporting requirement in the proposed rule to submit a written report to the NRC Regional Office no later than 15 days after discovery of the dose has also been retained in the final rule. We believe that the 15 day reporting period is justified by the more serious consequences associated with the higher reporting thresholds. It is important that the NRC has all of the information in the written report as soon as possible to evaluate the event and to determine if any follow-up actions are available. The rule language recognizes that the licensee may not have all of the final information on the event at the time the report is submitted to NRC.

Issue 7: Were There any Other Changes Made in This Section Between The Proposed and Final Rules?

Response. Yes. The NRC amended the title of this section to state more correctly that this section includes both reporting and notification requirements following a dose to an embryo/fetus or nursing child that exceeds the thresholds in § 35.3047.

We amended paragraph (b)(2) to read '' * * * permanent functional damage to an organ or a physiological system of the child * * *'' to make it clear that this reporting criterion applies to the nursing child.

We combined paragraphs (d)(1)(vi) and (vii) in the proposed rule into one paragraph [(d)(1)(vi)] in the final rule because they both address actions or improvements that have been taken, or are planned, to prevent recurrence of a medical event.

We reworded paragraphs (d)(1)(v)and (vi) in the final rule to read ''the effect, if any, on the embryo/fetus or the nursing child;'' and ''what actions, if any, have been taken, or are planned, to prevent recurrence.'' We added the words ''if any'' and ''are planned'' because there might not be any effect or any actions taken at the time the event is reported. We deleted paragraph (d)(1)(vi) in the proposed rule because it was duplicative of paragraph (d)(1)(vii).

We added a new paragraph (d)(1)(vii) to require that the written report include a certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not. This provides NRC with documentation that the pregnant individual or mother was notified. We made this revision because notifying these individuals is important enough to warrant documentation that the individual(s) was notified. In addition, we believe that it is important that the licensee notify the pregnant individual or mother so that she can be actively involved in any decision about remedial or prospective health care following the event.

We amended paragraph (e) [paragraph (d) of the proposed rule] in the final rule. The words ''when appropriate'' were deleted from the last sentence in paragraph (d) of the proposed rule because the intent was covered by the phrase ''may be made'' in the same sentence.

We combined proposed paragraphs (e), (f), and (g) into one paragraph so the format of this section is similar to the section on reporting medical events.

Paragraph (h) of the proposed rule that required the licensee to furnish the mother, or responsible relative or guardian, with a written report was deleted in the final rule. Instead, paragraph (e) in the final rule requires licensees to inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees are

required to provide such a written description to the individual, if requested. We believe that a written description would be especially useful to an individual who needs to make decisions about any follow-up medical care, and provides the individual a permanent record to refer to for information about the event.

We added paragraph (f) to the final rule to require that licensees annotate a copy of their report to the NRC about the event and provide it to the referring physician, if other than the licensee, within 15 days after discovery of the event. We believe that it is important for the referring physician to have all the available documentation about the event to support any decision about remedial or prospective health care. The 15-day time period to provide the referring physician with a copy of the record was based on paragraph (d) which requires a licensee to submit a report to the NRC within 15 days. We have attempted to have consistency in the requirements in Subparts L and M, where possible, to simplify compliance with the recordkeeping and reporting requirements.

Section 35.3067, Report of a leaking source

Issue: Where There any Changes Made in This Section Between the Proposed and Final Rules?

Response. Yes. The NRC changed the title of this section so that it refers to a single report. This change makes the title of this section consistent with the titles of the other sections in Subpart M.

We made this section more performance based by using ''the results of the test'' instead of the more detailed requirements of ''the measured activity of each test sample expressed in microcuries'' and ''a description of the method used to measure each test sample.'' These changes are consistent with changes made in response to comments on § 35.2067, Records of leaking sources.

IV. Summary of Comments on Agreement State Compatibility and Responses to Comments

Part 1: General Questions

Issue 1: How does NRC Determine if a Requirement Should Be Given a Health and Safety (H&S) Classification?

Comment. Several commenters expressed a concern regarding the compatibility categories, especially those designated as ''D (H&S)''. Commenters stated that the (H&S) classification has nothing to do with compatibility but does apply to adequacy of a State's radiation control program. They further stated that, if the NRC finds it necessary to use this classification, then it should define the ''significant safety issues'' that led to the (H&S) designation. Other commenters stated that H&S designations for Agreement State requirements is a ''back door'' to compatibility requirements and may be unevenly and/or inappropriately enforced. Commenters recommended that if a requirement must be adopted by an Agreement State in order for that State's program to be found ''adequate,'' the requirement should be assigned a ''compatibility'' designation. H&S designations should be assigned only when a requirement has a direct Part 20 connection.

Response. On September 3, 1997, the Commission approved an Adequacy and Compatibility Policy for Agreement State Programs. This policy was developed in an open environment, with early and substantive involvement by Agreement State representatives. Management Directive 5.9, ''Adequacy and Compatibility of Agreement State Programs'' (Adequacy and Compatibility Policy) provides guidance on applying the Adequacy and Compatibility Policy to Agreement State program elements including regulations.

The assignment of compatibility categories to each requirement in the revised rule has been made in accordance with the Adequacy and Compatibility Policy. The compatibility category assignments are needed to assure that byproduct material is used with a minimum level of safety nationwide. Those program elements (including regulations) which are not required for compatibility, as noted in the Adequacy and Compatibility Policy, may be required because of their health and safety (H&S) significance. The NRC has reviewed and revised, where appropriate, the chart detailing the compatibility categories for each requirement in the final rule. Each requirement in the rule, identified for compatibility or adequacy, has an accompanying rationale explaining its health and safety significance or its need based on consistency between NRC and Agreement State programs.

NRC conducts performance based reviews of Agreement State programs in accordance with the Integrated Materials Performance Evaluation Program (IMPEP). Findings of Adequacy and Compatibility for each Agreement State program are made by a management review board (MRB) consisting of senior NRC managers along with a manager from an Agreement State. These findings are made based on a number of factors, including regulations.

Under the Adequacy and Compatibility Policy, and the review of Agreement State programs under IMPEP, the Agreement States are provided flexibility in administering their programs. Regulations and other program elements identified as having adequacy or health and safety significance may be addressed through the promulgation of compatible regulations or the adoption of other legally binding documents. Final findings of Agreement State program adequacy and compatibility are made by the MRB based on their assessment of the entire program, not just its regulations. This process assures a level of consistency in the review of Agreement State programs. Each Agreement State program director is afforded an opportunity to appear before the board to explain his or her State's performance and answer questions from the MRB.

Issue 2: What Flexibility Should Be Given to Agreement States?

Comment. A commenter stated that Part 35 should not be a matter of compatibility for the Agreement States beyond requiring that states have a system for authorizing the medical use of byproduct material. Another commenter stated that the Agreement States should be allowed to regulate medical users as appropriate and as needed. They believed that the rule should be a low compatibility issue. Another commenter stated that the proposed Part 35 will deal a death blow to the Agreement State Program by demanding that every Agreement State adopt the essential portions of NRC's new Part 35 under threat of being incompatible and inadequate. The commenter stated that the Agreement States want flexibility. A commenter also expressed that this may cause Agreement States to give back their programs.

On this same topic, a commenter stated that nearly all of NRC's policy on Agreement State adequacy and compatibility should be rejected. The practices of medicine and pharmacy have no ''transboundary implications'' and should be changed from compatibility Category ''B'' to ''D'' because they are State functions. All compatibility category ''C'' items should be changed to ''D'' because they are too restrictive. All ''Health and Safety'' (H&S) requirements for adequacy should be removed because they are not necessary for ''Health and Safety.'' The commenter further stated that, ''Health and Safety'' is accomplished by starting

with qualified professionals who follow professional standards.

In contrast, commenters stated that a uniform or relatively uniform approach nationwide between Agreement State regulations and NRC regulations can be worked out and can be adopted. In particular, the American Association for Nuclear Cardiology requested that the NRC require the new Part 35 requirements to be at least a level C compatibility for the Agreement States.

Response. The Adequacy and Compatibility Policy for Agreement States Programs is explained in response to Issue 1. The assignment of the specific compatibility categories to the requirements in the revised rule is necessary to assure that byproduct material is used with a uniform level of radiation safety nationwide. This is different from the State regulation of medicine and pharmacy, which addresses global safety and competency issues.

Issue 3: Was the Comment Period on the Proposed Rule and on Compatibility Assignments Extended?

Comment. Agreement State representatives commented that the comment period was too brief to allow a comprehensive review of the rule, the licensing guide, and the compatibility listing. They also asked that we provide a listing of essential objectives for each section and why particular designations were assigned. In addition, Agreement State representatives asked that the comment period for the rationale for compatibility assignments should be extended up to 90-days after publication of the listing. They further stated that the degree of flexibility allowed the Agreement States is an important issue and should not be omitted from the discussion because information was not available in a timely manner.

Response. Supplement III of this document contains more detailed discussion of the comments that we received on the length of the comment period. As a result of public comment, we extended the comment period on the proposed rule from November 12, 1999 to December 16, 1999.

The proposed rule contained a brief explanation of the compatibility assignments that were made for the proposed rule. Subsequent to that publication, we received requests from Agreement State representatives to provide supporting documentation for how the assignments were made and to provide the essential objectives for each section. This information has been made available to the Agreement States in an All Agreement States letter, dated January 4, 1999. We asked that the States provide comments and suggestions on the compatibility designations by February 12, 1999.

The NRC considered all comments received on the compatibility designations and, where appropriate, made changes to either the assignment or to the rationale for the assignment. Section X of this document contains a summary of the compatibility designations. A more detailed compatibility chart which provides the essential objectives for each section and why particular designations were assigned is posted on the NRC Website at *http://www.hsrd.ornl.gov/nrc/home.html.* Click on [NRC-State Letters] and then select Part 35 Compatibility Chart.

Issue 4: How has NRC Incorporated Comments From the Agreement States on Agreement State issues?

Comment. A commenter questioned how the Agreement States comments were considered during the rulemaking.

Response. In the early stages of the rulemaking process, the NRC established a working group and a steering committee comprised of State personnel and NRC staff. One member of the NRC working group was also a member of the Conference of Radiation Control Program Director's, Inc., SR–6 Committee. This Committee is responsible for revising Part G, ''Medical Use of Radionuclides,'' of the Suggested State Regulations. As such, there was a considerable amount of information exchanged between the States and the NRC staff during the development of the proposed and final rule. We also discussed the revision of Part 35 with representatives of the Agreement States at the 1997, 1998, and 1999 annual meetings of the Organization of Agreement States. In addition, we received numerous comment letters from the States, all of which were considered in developing the final rule.

Technical comments and our response to the comments are discussed under the specific section headings. More general comments or comments that pertain exclusively to the compatibility level assigned to the requirement are discussed in this section.

Part 2—Comments on Compatibility Designations

The NRC received numerous comments on the compatibility designations assigned to specific sections. The following part provides the comments and our response to the comments. In many cases, but not all, we made changes to the compatibility designation based on the comment.

Part 20—Standards for Protection Against Radiation

Section 20.1301, Dose Limits for Individual Members of the Public

Comment. A commenter stated that this requirement should not be a compatibility category A. The compatibility category for this requirement should be D.

Response. This section meets the criteria for compatibility category A because it is an NRC program element which is generally applicable and is a dose limit. No change is required.

Part 35—Medical Use of Byproduct Material

Section 35.6, Provision for Research Involving Human Subjects

Comment. A commenter stated that compelling Agreement States to adopt this requirement does not reflect that there may be other criteria affecting human research subjects.

Response. A further review of this section indicates that Agreement States should adopt this requirement in order to avoid a gap in the consistent nationwide application of this Federal policy. The compatibility category was changed from ''D'' to ''C.'' The NRC also added a requirement to the section indicating that nothing in this section relieved licensees from complying with the other requirements in Part 35.

Section 35.24, Authority and Responsibilities for the Radiation Protection Program

Comment. A commenter stated that this requirement should be classified compatibility category D, not D Health and Safety (H&S). The commenter indicated that, while management should be responsible for the areas identified here, there may be other ways to ensure radiation safety. Further, in the opinion of the commenter, the intent of this requirement will be defeated for small facilities where the AU/RSO is management's designee.

Response. Section 35.24 in the final rule is assigned a compatibility category D, with the exception of paragraphs (b) and (f). These two paragraphs are assigned to compatibility category H&S. The H&S compatibility category provides the Agreement States with the flexibility needed to use other methods such as legally binding requirements to achieve the essential objective of this rule. In addition, § 35.24(b) and (f) meet the two failure test criteria for the assignment of compatibility category H&S. This designation provides a

minimum level of safety in the implementation of a radiation protection program.

Section 35.40, Written Directives

Comment. A commenter stated that the requirement for a written directive may not be contained in the State's radiation regulations. Another commenter stated that written directives do not meet the definition for a compatibility category C in Subpart A, because it does not create a gap or a duplication. It was also noted that written directives are a compatibility category ''D (H&S)'' in Subpart B. Another commenter stated that written directives should not be designated compatibility category H&S and that there are other methods to ensure the right dose is delivered to the right patient (e.g., requiring the physician to be present during a therapy treatment).

Response. In the final rule, paragraphs (a) and (b) of § 35.40, ''Written Directives,'' are assigned a compatibility category H&S. The NRC believes that it may be possible to ensure the right dose is delivered to the right patient if a legally binding requirement is in effect and there is some documentation by the physician in the routine radionuclide use log. In accordance with the Policy on Adequacy and Compatibility for Agreement State Programs, legally binding requirements may be acceptable in lieu of a specific regulation on written directives if the essential objectives of this rule are achieved. Section 35.40 meets the two failure test criteria for the assignment of compatibility category H&S. This designation provides a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event.

Section 35.61, Calibration of Survey Instruments

Comment. A commenter stated that the requirement in § 35.61 to note the date of the calibration on an instrument should not be a compatibility category H&S. The length of time for record retention is not a compatibility category H&S and should be designated a compatibility category C in all areas of the regulations.

Response. The NRC agrees with the commenter that the requirement to note the calibration date on a survey instrument and the record retention requirement should not be a compatibility category H&S. Therefore, these requirements have been revised from H&S to a compatibility category D. All of the other requirements in § 35.61 remain compatibility category H&S.

Section 35.63, Determination of Dosages of Unsealed Byproduct Material for Medical Use

Comment. A commenter stated that there may be some confusion regarding the compatibility category assigned to the requirement covering radiopharmaceutical dosages prepared by the medical use licensee under 10 CFR 35.63 versus those prepared by a commercial pharmacy/manufacturer under 10 CFR 32.72.

Response. Both medical licensees and the commercial preparer of radiopharmaceuticals must determine and record the activity of each dosage intended for medical use. Therefore, this requirement is a compatibility category H&S.

Section 35.67, Requirements for Possession of Sealed Sources and Brachytherapy Sources

Comment. A commenter stated that paragraph (a) should be a compatibility category C. The commenter believed that licensees can develop better procedures and should have the opportunity to submit them for review and approval by the licensing agency.

Response. Section 35.67(a) meets the two failure test criteria for the assignment of compatibility category H&S. This designation assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

Comment. A commenter stated that paragraph (f) rather than (e) should be a compatibility category D and paragraph (e) should be a compatibility category ''D (H&S)''. Another commenter stated that paragraph (f) which provides a waiver of leak test requirements does not meet the criteria for compatibility category H&S.

Response. Paragraph (e) is a compatibility category H&S because the technical requirements are already addressed in Part 20 and Part 30 and the actual reporting requirement for leaking sources is contained in § 35.3067 which is a compatibility category C. We agree with the commenters. The compatibility category for paragraph (f) was revised from H&S to D.

Section 35.70, Surveys of Ambient Radiation Exposure Rate

Comment. A commenter questioned the need for a compatibility category H&S for paragraph (b).

Response. The NRC agrees with the commenters and have revised this section to indicate that § 35.70(b) is assigned a compatibility category D.

Section 35.75, Release of Individuals Containing Radioactive Drugs or Implants Containing Byproduct Material

Comment. A commenter stated that 10 CFR 35.75, which has been assigned a compatibility category C, should be changed to category B due to significant transboundary implications.

Response. The assignment of a compatibility category C to this requirement is appropriate because the term transboundary applies to the use of byproduct material by licensees which operate in multiple locations. The compatibility category C designation provides a minimum level of safety, while providing some flexibility to Agreement States to be more restrictive.

Section 35.80, Provisions of Mobile Medical Service

Comment. A commenter did not agree with the original basis for designating this section as D compatibility. They disagreed with the following statement: ''since there is no potential for medical use of byproduct material in other regulatory jurisdictions under reciprocity'' the section is designated a D compatibility.''

Other commenters commented on specific paragraph designations. A commenter stated that paragraph (a)(1) should not be a compatibility category H&S issue. Another commenter stated that paragraph (a)(4) should be a compatibility category H&S issue, but that the designation is inconsistent with the requirements for fixed facilities. (Note: Fixed facilities have to conduct surveys only for procedures requiring a written directive (§ 35.70)).

Response. The Agreement State representatives informed the NRC staff that not all Agreement States authorize mobile services and that there are a number of additional State professional and technical licensing issues which complicate this activity. The medical use of byproduct material (diagnostic or therapeutic) as a mobile service has been designated a compatibility category D for all Agreement States (not required for compatibility) and category H&S for those Agreement States which authorize mobile services. This designation H&S assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

The NRC agrees with the specific comments on paragraphs (a)(1) and (a)(4). The compatibility categories were revised from H&S to D in these sections.

Section 35.92, Decay-In-Storage

Comment. A commenter stated that this section should not be a

compatibility category H&S issue. The failure scenario is in error in that it assumes waste would be placed in ordinary trash if storage of isotopes with longer or shorter half-lives were permitted. Permitting decay-in-storage does not mean material that has not decayed would be placed in ordinary trash.

Response. This section is a compatibility category D for those States that choose not to allow the decay-in-storage option. For States allowing this option, the compatibility category is H&S. The two or fewer failure test scenario was reworded to better reflect the importance of the H&S assignment for this requirement.

Sections 35.100, Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required and 35.200, Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive Is Not Required

Comment. A commenter questioned the assignment of a compatibility category H&S to §§ 35.100 and 35.200 because they are very low risk procedures.

Response. Both requirements meet the two or fewer failure test scenario detailed in Management Directive 5.9 for the assignment of compatibility category H&S. These provisions assist in establishing a minimum level of safety in the medical use of agreement materials by reducing the likelihood of a medical event.

Section 35.390, Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required

Comment. A commenter believed that Agreement States should have the option of adopting higher standards for training even if it means the state would become ''incompatible.''

Response. A compatibility category B was assigned to this requirement, as well as all of the other training and experience requirements in Part 35. This ensures that the training and experience requirements for the medical use of byproduct material are consistent between NRC and the Agreement States.

Section 35.432, Calibration Measurements of Brachytherapy Sealed Sources

Comment. A commenter stated that this requirement should not be a compatibility category C.

Response. This requirement was assigned a compatibility category H&S which provides a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event.

Section 35.604, Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit

Comment. A commenter stated that the requirement for after implant surveys is not appropriate for a compatibility category C, since it is a Part 20 requirement.

Response. The NRC agrees with this comment and has changed the requirement to a compatibility category H&S.

Sections 35.610, Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

*Comment.*A commenter stated that § 35.610 should be compatibility category C, as there can be other ways of meeting the essential objectives.

Response. Section 35.610 meets the two or fewer failure test criteria for the assignment of compatibility category H&S. This designation assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

Section 35.615, Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Comment. A commenter stated that § 35.615 should be compatibility category C, as there can be other ways of meeting the essential objectives.

Response. Section 35.615 meets the two or fewer failure test criteria for the assignment of compatibility category H&S. This designation assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure.

General Comments on Training

Comment. A commenter stated that when the Part 35 rulemaking becomes effective, Agreement States that have more strict training and experience requirements for non-board certified physicians will not be able to accept individuals who have met the less restrictive requirements needed to become AUs on NRC licenses as authorized.

Response. When the final Part 35 becomes effective, the Agreement States will have up to 3 years to adopt compatible regulations. The training and experience criteria for physicians is a compatibility category B which means that the requirement has significant direct transboundary implications. Agreement States' requirements should be essentially identical to those of the NRC so that there are consistent training and experience requirements for the medical use of byproduct material. Non-board certified physicians will continue to be afforded the opportunity to present alternate credentials on a case-by-case basis.

V. Summary of Changes Made Between the Current Part 35 and the Revised Part 35

Subpart A, General Information, contains general information regarding medical use of byproduct material.

Section 35.1, Purpose and scope, was amended to specify that Part 35 provides for the radiation safety of workers, the general public, patients, and human research subjects. The NRC included the phrase ''patients, and human research subjects'' to make it clear that the provisions of this rule apply to the radiation safety of those individuals. This addition is consistent with the revision of the Medical Use Policy Statement that was published in the **Federal Register** on August 3, 2000 (65 FR 47654). We also added a reference to Part 171, ''Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed By NRC.'' This change makes it clear that the provisions in Part 171 apply to medical licensees.

Section 35.2, Definitions, was amended. The NRC either deleted, revised, or added specific definitions based on the use of the terms within Part 35. Each category of action is discussed separately.

Deleted Definitions

The NRC deleted the following terms because they do not appear in the final rule: as low as is reasonably achievable (ALARA), dental use, diagnostic clinical procedures manual, ministerial change, misadministration, podiatric use, recordable event, and teletherapy physicist.

Revised Definitions

The NRC revised the definitions of *address of use* and *area of use* to clarify that they also include the building where byproduct material is prepared for use. This recognizes that licensees not only receive, use, and store byproduct material, but, in the case of medical licensees, they may also prepare the material for use.

The NRC revised the definition for *authorized nuclear pharmacist* (ANP) to eliminate the specific board certifications by name and to refer to the specific section(s) in Part 35 containing the requirements the individual must meet to be considered an ANP. We deleted the reference to the specific board certifications because the regulatory text in Part 35 no longer incorporates a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements. In place of listing the boards, the final rule provides for NRC recognition of the boards. We revised the definition of ANP to include individuals identified as ANPs on a specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy; a permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy; a permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or a permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy. In addition, an ANP can be an individual identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy which has been given authorization to identify authorized nuclear pharmacists or an individual designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

The NRC revised the definition for an *authorized user* (AU) to eliminate the specific board certifications by name and to refer to the specific section(s) in Part 35 containing the requirements the individual must meet to be considered or an AU. We deleted the reference to the specific board certifications because the regulatory text in Part 35 no longer incorporates a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements. In place of listing the boards, the final rule provides for NRC recognition of the boards. We revised the definition of AU to include individuals identified as AUs on a Commission or Agreement State license that authorizes the medical use of byproduct material; a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material; a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

The NRC revised the definition for a *brachytherapy source* to acknowledge current practices within the radiation oncology field. In addition, we deleted the word ''sealed'' from the definition to include sources that do not meet the definition of ''sealed source,'' i.e., radioactive plated, embedded, and activated sources.

The NRC revised the definition of *management* to recognize an individual having the authority to manage, direct, or administer the licensee's activities who may not have the title of Chief Executive Officer.

The NRC amended the definition of *medical use* to replace the word ''therefrom'' with the phrase ''from byproduct material'' because the regulations in Part 35 apply only to the medical use of byproduct material.

The NRC replaced the definition of *mobile nuclear medicine service* with a definition for *mobile medical service* because it is a broader term that encompasses all modalities that could be performed by a mobile medical service.

The NRC revised the definition of *output* to refer to the exposure rate or dose rate coming from a brachytherapy source, remote afterloader, or gamma stereotactic radiosurgery unit. The current rule only addresses the output from a teletherapy unit.

The NRC revised the definitions of *prescribed dosage* and *prescribed dose*. As modified, the definition of prescribed dosage allows the AU to prescribe a range of activity, without reference to the diagnostic clinical procedures manual. The term unsealed byproduct material in this definition replaces the term radiopharmaceutical. We added a reference to remote afterloaders to the definition of prescribed dose.

The NRC revised the definition of *Radiation Safety Officer* (RSO) to include a reference to the specific requirements an individual must meet in order to be authorized as an RSO. This change makes the definition of RSO consistent with the definitions of ANP, AU, and authorized medical physicist (AMP). We also amended the definition to state that an RSO could also be an individual identified on a specific medical use license issued by the Commission or Agreement State license or a permit issued by a Commission master material licensee.

The NRC revised the definition of *written directive* to delete the provisions for the date the directive was signed, the signature of the AU before administration of any byproduct material or radiation from byproduct material to a specific patient or human research subject, and the specific information that must be included in written directives. These provisions were considered to be substantive requirements and were moved to § 35.40, Written directives.

New Definitions

The NRC added the following definitions either because they are used in the final Part 35 or the stakeholders asked that definitions of the terms be added to help clarify regulatory text. Definitions were added for the following terms: authorized medical physicist, brachytherapy, client's address, high dose-rate remote afterloader, low dose-rate remote afterloader, manual brachytherapy, medical event, medium dose-rate remote afterloader, patient intervention, preceptor, pulsed dose-rate remote afterloader, Sealed Source and Device Registry, stereotactic radiosurgery, structured educational program, teletherapy, temporary job site, therapeutic dosage, therapeutic dose, treatment site, type of use, and unit dosage.

The NRC amended § 35.5, Maintenance of records, to insert ''and'' in the current phrase ''drawings and specifications.''

The NRC amended the title of § 35.6 to read Provisions for the protection of human research subjects. We also restructured this section to make it easier to read. We added an introductory paragraph to make it clear that research permitted under § 35.6 may only be performed using byproduct material that is already authorized for medical use by the license. For example, if a licensee is authorized to use byproduct material for medical use under §§ 35.100, 35.200, and 35.300 and Cs-137 for calibration of survey instruments, it cannot conduct medical research using the Cs-137 source. However, the same licensee can conduct research using materials authorized under §§ 35.100, 35.200, or 35.300.

We added paragraph (d) to codify the Commission's intent that § 35.6 does not relieve licensees from complying with other provisions in Part 35 and that all relevant radiation safety provisions of Part 35 are applicable to research involving human subjects. This position is further discussed in the regulatory history of § 35.6. For further information on this issue, see the **Federal Register** of December 2, 1994 (59 FR 61767).

The NRC made no changes in § 35.7, FDA, other Federal, and State requirements.

The NRC amended § 35.8, Information collection requirements; OMB approval, to reflect the renumbering of some sections within the rule and the additional recordkeeping and reporting sections which are in separate subparts in the new rule.

Section 35.10, Implementation, is a new section that discusses the provisions for implementing the final rule. A detailed discussion of the implementation provisions can be found in Section IX of the **SUPPLEMENTARY INFORMATION.** This section replaces the current § 35.999, Resolution of conflicting requirements during transition period.

The NRC revised § 35.11, License required. Paragraph (a) was revised to state more clearly that a person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State or as allowed in paragraphs (b)(1) and (b)(2) of this section. We added ''prepare'' to recognize that medical use licensees may also prepare the byproduct material for use and need a license to do so. We amended paragraphs (b)(1) and (b)(2) to reflect that the requirements for supervision in the current § 35.25 were replaced by the requirements in the final § 35.27.

The NRC revised § 35.12, Application for license, amendment, or renewal.

We revised paragraph (a) to state that any application for a license, amendment, or renewal must be signed by the applicant's or licensee's management. The current rule indicates that any person may apply if the application is for medical use not sited in a medical institution and that only management may apply for a license if the application is for use in a medical institution. We believe it is important that management apply for a license, regardless of where the byproduct material is used, because NRC holds the licensee responsible for any actions of its employees.

We revised paragraph (b) to address license applications for uses authorized under §§ 35.600 and 35.1000. Therefore, the current paragraph (c) was no longer needed and was deleted. We no longer require licensees to have separate licenses for teletherapy or gamma stereotactic radiosurgery units. In addition, paragraph (b) lists the items that must be submitted to NRC in support of a license application. The new paragraph (c) provides a list of the items that must be submitted to NRC in support of a license amendment. The lists in paragraphs (b) and (c) codify existing licensing practices. Finally, we amended paragraphs (b) and (c) to delete the reference to the regulatory guides. Guidance for completing an application is in NUREG–1556, Vol. 9 (draft), ''Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.'' NUREG–1556, Vol 9 (draft), is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

We deleted the statement in the current paragraph (d) that referenced where to find copies of regulatory guides, application forms, or where to submit an application or an amendment request. This information is not needed in the regulation. The new paragraph (d) addresses applications for medical use of byproduct material as described in § 35.1000, i.e. applications that are not specifically included in Subparts D through H of the final rule and are referred to as ''emerging technologies.'' The current rule does not address emerging technologies. Therefore, it does not provide for efficient licensing of emerging technologies. Paragraph (d)(1) provides a list of the additional information needed by NRC to approve a license or license amendment for a use not specifically addressed in Subparts D through H of the new rule. This additional submittal will provide NRC with information on the radiation safety aspects of the specific medical use of the material. Applicants for uses under § 35.1000 must also submit the information required by paragraph (b) and (c) of this section.

The NRC revised § 35.13, License amendments. We revised paragraph (a) to clarify that a licensee must apply for a license amendment before it ''prepares'' byproduct material for a type of use that is not authorized on the licensee's current license. Paragraph (a) was also changed to reference ''type of use'' rather than ''clinical procedure.'' In addition, paragraph (a) was expanded to include AUs, AMPs, and ANPs identified on a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy or by a commercial nuclear pharmacy that has been given authorization to identify authorized nuclear pharmacists. The term ''type of use'' is defined in Part 35 and is more appropriate for use in this requirement. We added the reference to an AMP to paragraph (b). A medical use licensee is no longer required to amend its license before allowing anyone to work as an AMP if that individual meets the training and experience requirements in § 35.51(a), and the training and experience requirements were met within the 7 years preceding the date of the application in accordance with § 35.59. In addition, paragraphs (a) and (b) were reworded to indicate clearly the subject of each paragraph.

In paragraph (c), we deleted the requirement for a licensee to apply for a license amendment if the teletherapy physicist changes, provided the individual meets the requirements in §§ 35.51(a) and 35.59. This change is consistent with licensing requirements for AUs and ANPs. Additionally, in the revised § 35.24(c), the Commission recognizes that unusual conditions may arise when the RSO leaves a licensee with little to no advance warning. In this event, the licensee may want to consider using an AU or other individual qualified to be an RSO to fill the position, pending appointment of a new RSO. Under these conditions, the licensee must move expeditiously to permanently fill the position of RSO and should contact the appropriate NRC regional office and explain the situation.

We revised paragraph (d) to require the licensee to apply for and receive a license amendment before it receives byproduct material in excess of the amount or in a different form or it receives a different radionuclide than is authorized on the license. This change clarifies that the requirement is tied to a licensee's authorization to possess, not order, byproduct material and to clarify when an amendment is needed. For example, if a license authorizes possession of any byproduct material identified in §§ 35.100, 35.200, and 35.300, in any chemical and/or physical form, a licensee would be required to obtain a license amendment if it wanted to possess sealed sources for manual brachytherapy (§ 35.400). This same licensee would not need to amend its license if it wanted to use sodium iodide I–131 for thyroid carcinoma because that use is authorized by § 35.300. Further, an amendment would not be required if the licensee wanted to use Tc-99m labeled methylene diphosphonate (MDP) rather than Tc-99m labeled sestamibi because the use is authorized by § 35.200.

To reduce regulatory burden, we deleted the requirement in paragraph (e) for a licensee to apply for a license amendment if there is a change in the areas where byproduct material is used under either § 35.100 or § 35.200. In addition, the requirement in the current paragraph (e) for a licensee to apply for an amendment before it changes the

address(es) of use identified in the application or on the license was moved to the final paragraph (f).

We added a new paragraph (g) that requires a licensee to apply for a license amendment if it revises the procedures that must be submitted in accordance with § 35.12(b)(2), where the revision reduces radiation safety. This applies to procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

The NRC revised § 35.14, Notifications. Paragraph (a) was revised to include a requirement for the licensee to notify NRC no later than 30 days after the date the licensee permits an individual to work as an AMP under § 35.13(b), which is comparable to the notification requirements for AUs or ANPs. This change was needed because we would like to be notified when an AMP who has been approved by the licensee begins work. (Reference change made to § 35.13(b)). We revised paragraph (b) to require that the licensee notify NRC when an AMP permanently discontinues performance of duties under the license and to require that a licensee notify NRC when the licensee changes its name. This provision applies only if there is no change in ownership, as described in § 30.34 of this chapter. If there is a change in ownership, the licensee must take appropriate action to have its license amended before the transfer occurs. We also added a requirement to paragraph (b) for a licensee to notify NRC of any changes in areas where byproduct material is used in accordance with either § 35.100 or § 35.200. These revisions to the requirements for notifications were warranted because of the associated revisions to the requirements for license amendments in § 35.13.

The NRC amended § 35.15, Exemptions regarding Type A specific licenses of broad scope, to add the term ''authorized medical physicist'' to paragraph (e). This change is needed because, under the revised requirements in § 35.13, broad scope licensees have the authority to appoint AUs, ANPs, or AMPs without applying for a license amendment if the individuals meet the approved criteria in Subparts B and D through H.

We added a new paragraph (f) to exempt broad scope licensees from § 35.14(b)(4), which requires licensees to notify NRC if there have been any changes in the areas where byproduct material is used in accordance with either § 35.100 or § 35.200. This provision for exemptions is consistent with the current exemption these licensees have from applying for a license amendment before they add to or change the areas of use identified in the application or on the license.

We added a new paragraph (g) to also exempt these broad scope licensees from § 35.49(a). This change codifies an exemption currently provided to these licensees through a standard license condition. NRC's medical use licensees with a Type A specific license of broad scope currently receive a standard license condition that exempts the licensee from only receiving sealed sources or devices manufactured from licensees with medical distribution licenses issued in accordance with § 32.74. This change replaces the license condition.

The NRC revised § 35.18, License issuance. Paragraph (a) lists the conditions that must be met in order for the Commission to issue a license. We added requirements for a mobile medical service license as paragraph (b). The NRC will issue a license for mobile medical service if the applicant meets the requirements specified in paragraph (a) of the section and if the individual or human research subject to whom the applicant administers byproduct material, or radiation from byproduct material, may be released following treatment in accordance with § 35.75. The later provision is necessary because mobile medical service licensees do not have the capability of controlling individuals who cannot be released under § 35.75.

The NRC amended § 35.19, Specific exemptions, to delete the statement that the Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI). This statement is a matter of Commission policy rather than a regulatory requirement.

Subpart B, General Administrative Requirements, contains the general administrative requirements regarding medical use of byproduct material.

The NRC deleted the current § 35.20, ALARA program. ALARA is discussed in § 20.1101, Radiation protection programs, and medical licensees must comply with the requirements of that section. That section requires, in part, that a licensee develop, document, and implement a radiation protection program and use, to the extent practicable, procedures and engineering controls to achieve occupational doses and doses to members of the public ALARA. Therefore, we do not believe that the current § 35.20 is needed in light of the requirements in § 20.1101. A medical use licensee should have flexibility in developing, maintaining, and implementing a radiation protection program that meets the requirements of Part 20.

The NRC deleted the current § 35.21, Radiation Safety Officer. The requirements in paragraph (a) were moved to § 35.24. The list of the RSO's duties in paragraph (b) was deleted because it is overly prescriptive and in some cases overlaps with the requirements in § 20.1101. We believe that the licensee should have flexibility in developing, maintaining, and implementing its radiation protection program, including establishing the RSO's duties.

The NRC deleted the current § 35.22, Radiation Safety Committee. The issue of whether the NRC should require a Radiation Safety Committee (RSC) was identified as a cross-cutting issue. Therefore, this issue was discussed at public meetings throughout the rulemaking process. Comments received on this topic are discussed in Section III of the **SUPPLEMENTARY INFORMATION.** The basic requirement for certain medical licensees to have an RSC to oversee all uses of byproduct material permitted by the license was moved to § 35.24. However, the requirement was modified so that only licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F and H, or two or more types of units under Subpart H, are required to establish an RSC. Several other requirements that are currently in § 35.22 were also moved to § 35.24 and are discussed under that section. However, most of the requirements that are currently in § 35.22 have been deleted to provide licensees with more flexibility in how they use the Committee to oversee the radiation safety aspects of the medical use of byproduct material.

The NRC deleted the current § 35.23, Statements of authority and responsibilities. The requirements in this section, with some modifications, were moved to § 35.24.

The NRC added a new § 35.24, Authority and responsibilities for the radiation protection program. A number of the current, prescriptive requirements associated with the radiation protection program have been deleted to provide licensees more flexibility in achieving the objective of radiation safety.

Paragraph (a) requires licensee management to approve, in writing, licensing actions; individuals before allowing them to work as an AU, ANP, or AMP; and radiation protection program changes that do not require a license amendment and are permitted under § 35.26. We believe that licensee

management should be responsible for these approvals as part of their overall responsibility for the radiation protection program. This is a change from the current § 35.22, which gives the RSC the responsibility for two of these approvals: approval of individuals before allowing them to work as an RSO, AU, ANP, or AMP; and approval of radiation protection program changes that do not require a license amendment.

The requirement in paragraph (b) to appoint an RSO is currently in § 35.21. Paragraph (b) also includes a new requirement that the RSO agree, in writing, to be responsible for implementing the radiation protection program. The requirements in paragraphs (e) and (g), associated with the authorities, duties, and responsibilities of the RSO, are similar to the requirements in the current § 35.23.

Paragraph (c) includes a new provision that allows a licensee to have a temporary RSO for up to 60 days a year if the individual is qualified to be an RSO under §§ 35.50 and 35.59 and if the licensee meets the requirements for RSOs in paragraphs (b), (e), (g), and (h) of this section. We added this new provision so that licensees can appoint someone to fulfill the duties and responsibilities of the RSO in a timely manner, following the sudden departure of the permanent RSO named on the license. Licensees are required by § 35.14(b) to notify the Commission in writing no later than 30 days after an RSO permanently discontinues performance of duties under the license.

Paragraph (d) allows a licensee to simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has an individual that is qualified to be an RSO for each of the different types and uses of byproduct material permitted by the license.

Paragraph (f) contains a requirement for certain medical licensees to have an RSC to oversee all the uses of byproduct material permitted by the license. We modified the current requirement in § 35.22 so that only licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H, are required to establish an RSC. For example, licensees that are permitted on their license to use therapeutic quantities of unsealed byproduct material (§ 35.300) and manual brachytherapy (§ 35.400), or manual brachytherapy (§ 35.400) and low dose-rate remote afterloaders (§ 35.600), or teletherapy (§ 34.600) and gamma stereotactic radiosurgery (§ 35.600) would be required to have an RSC. However, we believe that many other medical licensees will also continue to use an RSC to oversee the use of byproduct material. Licensees should note that the requirement for an RSC is no longer limited to medical institutions, which means that it now also applies to free-standing clinics.

The new requirement for an RSC is much less prescriptive than the requirements in the current § 35.22. For example, paragraph (f) does not include the list of administrative requirements and committee tasks that are specified in the current rule. However, based on public comment, we have specified that the membership of the committee should include an AU of each type of use permitted by the license, the RSO, a representative of the nursing service, a representative of management who is neither an AU nor an RSO, and other members the licensee considers appropriate.

Paragraph (h) requires that the licensee retain a record of management's approval of actions in paragraph (a); written acceptance of RSO duties as specified in paragraph (b); and the duties, responsibilities, and authority of the RSO specified in paragraph (e) in accordance with § 35.2024, Records of authority and responsibilities for radiation protection programs.

The NRC deleted the current § 35.25, Supervision. The requirements in this section, with some modifications, were moved to § 35.27. The requirements in paragraphs (a)(3) and (b)(3) for periodic reviews of the work of supervised individuals were deleted because we believe that these requirements are too prescriptive. Licensees should have flexibility in how they evaluate supervised individuals because they are held responsible for their acts and omissions.

Section 35.26, Radiation protection program changes, is a new section. The requirements in this section are similar to the requirements in the current § 35.31, which was deleted. This section allows licensees to revise their radiation protection programs without Commission approval if the revision does not require an amendment in accordance with § 35.13; if the revision is in compliance with the regulations and license; if the change has been reviewed and approved by the RSO, and reviewed and approved in writing by licensee management; and if the affected individuals have been instructed on the revised program before the changes are implemented. This requirement provides licensees with flexibility to manage their radiation protection programs and clearly defines the situations that will not require Commission approval of an amendment to their license. The NRC believes that many licensees were reluctant to make changes to their current program because the term ''ministerial changes,'' as defined in the current § 35.2 and as used in the current § 35.31, was subject to misinterpretation. This change is intended to provide clear guidance to licensees on when they can revise their radiation protection programs without obtaining Commission approval.

We believe that it is important to instruct individuals in program changes, including those permitted under § 35.26, before they are implemented. This instruction may be provided in writing or orally and may be conducted on an informal or formal basis. It is not necessary to document that this instruction has been provided to affected parties, because these changes should not reduce radiation safety. At the time of inspection, NRC inspectors may question whether this instruction was provided.

Section 35.27, Supervision, is a new section. The requirements in this section are similar to the requirements in the current § 35.25, which was deleted. The NRC deleted the requirement to instruct individuals in the principles of radiation safety from paragraphs (a)(1) and (b)(1). This type of instruction is adequately addressed by § 19.12, Instructions to workers, of this chapter. We also amended paragraphs (a)(1) and (b)(1) to require that, in addition to the requirements in § 19.12, the licensee shall instruct supervised individuals in the written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions. We revised paragraph (a)(2) to clarify that the instructions, procedures, regulations, and license conditions that supervised individuals are required to follow are limited in this part to those involving the medical use of byproduct material. We deleted paragraphs (a)(3) and (b)(3) of the current § 35.25 because the licensee should have flexibility in evaluating employee performance. We amended paragraph (b)(2) to require supervised individuals to follow the instructions of the supervising AU or ANP regarding the preparation of byproduct material for medical use, written radiation protection procedures, regulations of this chapter, and license conditions. The statement in paragraph (c) that licensees are responsible for the acts and omissions of supervised individuals is similar to the statement in the current § 35.25(c).

The NRC deleted the current § 35.29, Administrative requirements that apply

to the provision of mobile service. The conditions for the Commission to issue a mobile medical service license were moved to § 35.18. The requirements in paragraphs (b) and (d) were moved to § 35.80. We deleted paragraph (c) because this requirement, which addressed the client's responsibilities, was viewed as being overly prescriptive. Mobile medical service licensees are required to comply with all the provisions of the license that authorize the use, possession, and transfer of material.

The NRC deleted the current § 35.31, Radiation safety program changes. The requirements, with some modifications, were moved to § 35.26 so that all the requirements pertaining to management of the licensee's radiation protection program appear in one area of Subpart B.

The NRC deleted the current § 35.32, Quality management program. The issue of whether the Commission should continue to require that a licensee develop, implement, and maintain a quality management program was identified as a cross-cutting issue and was discussed at public meetings throughout the rulemaking. Comments received on this topic are discussed in Section III of the **SUPPLEMENTARY INFORMATION.** Based on these comments, the Commission deleted the requirements for a quality management program. However, the Commission believes there are three elements of the current quality management program that should continue to be addressed in the rule for certain procedures: confirming patient identity, requiring written directives, and verifying dose. The requirements for these three elements are in §§ 35.40 and 35.41. However, we believe that licensees will continue to implement other elements of the current quality management program as part of the ''standard of care'' in medicine. In this regard, the Commission acknowledges that other factors, such as accreditation, have resulted in medical institutions adopting programs similar to those specified in the current rule.

The NRC deleted the current § 35.33, Notifications, reports, and records of misadministrations. The recordkeeping and reporting requirements were moved to Subparts L and M, respectively.

Section 35.40, Written directives, is a new section. This section contains requirements for the preparation of written directives that are similar to the requirements in the current §§ 35.2 and 35.32. Written directives are no longer required for administrations of sodium iodide I–125 because sodium iodide I–131 is primarily used now. Based on public comments and discussions with the ACMUI, changes were made in the information that must be included in written directives. For gamma stereotactic radiosurgery, the requirements for target coordinates, collimator size, plug pattern, and total dose have been deleted, and requirements for total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site have been added. For teletherapy, the requirement for overall treatment period has been deleted and a requirement for number of fractions has been added. For high dose-rate remote afterloading brachytherapy, requirements have been added for the dose per fraction and the number of fractions. For all other brachytherapy, before implantation, the requirements for number of sources and source strengths have been deleted and requirements for treatment site and dose have been added; and after implantation, but before completion of the procedure, a requirement for the number of sources has been added. Licensees should refer to § 35.41 for the requirements for procedures for administrations requiring written directives.

Section 35.41, Procedures for administrations requiring a written directive, is a new section. Paragraph (a) of this section requires licensees to develop, implement, and maintain written procedures to provide high confidence that, before each administration, the patient's or human research subject's identity is verified and that each administration is in accordance with the written directive. The specific details to be included in the written directives are in § 35.40. Paragraph (b) of this section specifies the items that must, at a minimum, be addressed in the procedures. The items identified in § 35.41 are viewed by the Commission as key elements of a program that will provide high confidence that byproduct material will be administered as directed by the AU. However, the regulations are not prescriptive about how these objectives are met, allowing licensees the flexibility to develop procedures to meet their needs. This section includes no requirement for submittal or approval of the procedures, as was previously required by the quality management rule. The recordkeeping requirements for this section are in § 35.2041, Records for procedures for administrations requiring a written directive.

The NRC retained § 35.49, Suppliers for sealed sources or devices for medical use with one modification. We added a new paragraph (b) to this section to permit noncommercial transfer of sealed sources or devices for medical use between Part 35 licensees that have a license to possess the source or device. Currently, licensees must obtain an amendment exempting them from the requirements in this section following initial distribution of the sealed source or device.

Section 35.50, Training for Radiation Safety Officer, is a new section. The training and experience requirements for an RSO were moved, with some modifications, from the current § 35.900, Radiation Safety Officer. Two changes made in the new section should be noted. First, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for RSOs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Second, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an RSO. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.50 will replace the current requirements in § 35.900, Radiation Safety Officer.

The NRC deleted the current § 35.50, Possession, use, calibration and check of dose calibrators. The requirements in this section, with some modifications, were moved to § 35.60.

Section 35.51, Training for an authorized medical physicist, is a new section. The training and experience requirements for an AMP were moved, with some modifications, from the current § 35.961, Training for teletherapy physicist. Three changes made in the new section should be noted. First, the title of this section was revised because the training and experience requirements in this section now apply to AMPs, rather than just teletherapy physicists, because requirements for gamma stereotactic radiosurgery units and remote afterloader units have been codified in the revised Part 35. Second, the listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for AMPs. In

place of listing the boards, the final rule provides for NRC recognition of the boards. Third, an individual must obtain written certification from a preceptor indicating that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AMP. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the Commission's changes to the training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.51 will replace the requirements in § 35.961, Training for authorized medical physicist.

The NRC deleted the current § 35.51, Calibration and check of survey instruments. The requirements in this section, with some modifications, were moved to § 35.61.

The NRC deleted the current § 35.52, Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides. The requirements in this section, with some modifications, were moved to § 35.60.

The NRC deleted the current § 35.53, Measurements of dosages of unsealed byproduct material for medical use. The requirements in this section, with some modifications, were moved to § 35.63.

Section 35.55, Training for an authorized nuclear pharmacist, is a new section. The training and experience requirements for an ANP were moved, with some modifications, from the current § 35.980, Training for an authorized nuclear pharmacist. One change made in the new section should be noted. The listing of specialty boards by name was deleted because the regulatory text in Part 35 will no longer incorporate a listing of specialty boards whose diplomates automatically fulfill the training and experience requirements for ANPs. In place of listing the boards, the final rule provides for NRC recognition of the boards. Section III of the **SUPPLEMENTARY INFORMATION** contains a detailed discussion of the new training and experience requirements in Part 35. Note, 2 years after the effective date of the final rule, § 35.55 will replace the current requirements in § 35.980, Training for an authorized nuclear pharmacist.

Section 35.57, Training for an experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist, is a new section that replaces the current requirements in §§ 35.901, 35.970, and 35.981, which will be retained for 2 years after the effective date of the final rule. All individuals who are identified as RSOs, teletherapy or medical physicists, AUs, and nuclear pharmacists on an NRC or Agreement State license or an equivalent permit issued before the effective date of the final rule will have ''deemed'' status after the rule becomes effective. These individuals do not need to comply with the new training and experience requirements unless they want to be named on a license for other types of uses.

The NRC deleted the current § 35.57, Authorization for calibration and reference sources. The requirements in this section, with some modifications, were moved to § 35.65.

Section 35.59, Recentness of training, is a new section that replaces the current requirements in § 35.972. Although this is not a new requirement, questions have recently been raised regarding whether all elements of the requirements must have been obtained in the last 7 years. The NRC expects that (1) either the individual has been board certified or has completed the training specified in the alternative pathway within the 7 years preceding the date of the application; or that (2) the individual has had related continuing education and experience since completing the required training and experience requirements. Continuing education and experience requirements are reviewed on a case-by-case basis, with input from the ACMUI, as necessary. We amended the text in the current § 35.972 to reference Subparts B, D, E, F, G, and H because the revised training and experience requirements appear in the subparts with their associated modality.

The NRC deleted the current § 35.59, Requirements for possession of sealed sources and brachytherapy sources. The requirements in this section, with some modifications, were moved to § 35.67.

Subpart C, General Technical Requirements, contains general technical requirements regarding medical use of byproduct material.

Section 35.60, Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material, is a new section that replaces the current §§ 35.50 and 35.52. This section addresses calibration of all instruments used to measure the activity of all unsealed byproduct materials, rather than only dose calibrators used to measure the activity of dosages of photon-emitting radionuclides (§ 35.50) or instruments used to measure dosages of alpha- or beta-emitting radionuclides (§ 35.52). The change recognizes that there are various types of instruments that can be used to measure the activity of unsealed byproduct materials. This change also gives licensees flexibility in developing a calibration program which meets their program needs.

The NRC deleted prescriptive calibration requirements in the current §§ 35.50 and 35.52. Paragraph (b) in the final rule requires that licensees calibrate the instrumentation in accordance with nationally recognized standards (e.g., voluntary consensus standards, such as ANSI N42.13–1986 (R 1993), ''Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides'') or with the manufacturer's instructions. This change makes the regulation more flexible, more adaptable to new technology, and more performance-based.

Licensees should note that they are required by § 35.63 to determine the activity of each dosage before medical use. If they use only unit dosages of radioactive drugs that meet the definition in § 35.2, then § 35.63 allows the licensee to determine the dosage by direct measurement of radioactivity; or by a decay correction based on the activity or activity concentration determined by either a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee (RDRC)-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration (FDA). If a licensee chooses to determine the dosage using this method, a licensee would not be required to possess instrumentation to measure the activity of the dosage, i.e., the licensee would not be required to comply with § 35.60. However, if a licensee chooses to reassay a unit dosage for the purpose of adjusting the activity, it would no longer be considered a unit dosage once it was altered, and the licensee must comply with § 35.60. This requirement is appropriate because confirmation of a dosage, or adjustment of dosages, must be based on properly-calibrated equipment.

The recordkeeping requirements for this section are in § 35.2060, Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

The requirements in the current § 35.60, with minor modifications, were moved to the final § 35.69.

Section 35.61, Calibration of survey instruments, is a new section that replaces the current § 35.51. The requirements in the current § 35.51 to

note the apparent exposure rate from a dedicated check source, as determined at the time of calibration; to attach a correction chart or graph to the instrument; and to check each survey instrument for proper operation with a dedicated check source each day of use were deleted. These changes give the licensee greater flexibility in calibrating instruments.

Paragraph (a) in the new § 35.61 now requires the licensee to calibrate survey instruments used to show compliance with this part and with Part 20 before first use, annually, and following a repair that affects the calibration. Paragraph (b) requires that survey instruments be removed from use if the indicated exposure rate differs from the calculated exposure rate by more than 20 percent. Previously, there was no threshold for removing instruments from use. The requirements in this section are generally consistent with ANSI N323–1978 (R 1993), ''Radiation Protection Instrumentation Test and Calibration.''

The recordkeeping requirements for this section are in § 35.2061, Records of radiation survey instrument calibrations.

The requirements in the current § 35.61, with minor modifications, were moved to the final § 35.69.

Section 35.63, Determination of dosages of unsealed byproduct material for medical use, is a new section that replaces the current § 35.53. This section requires licensees to determine and record the activity of each dosage before medical use. For unit dosages as defined in § 35.2, paragraph (b) allows the licensee to determine the dosage by direct measurement of radioactivity; or by a decay correction based on the activity or activity concentration determined by either a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or an NRC or Agreement State licensee for use in research in accordance with a RDRC-approved protocol or an IND protocol accepted by the FDA. Because the unit dosages have been assayed by the Part 32 licensee or by a licensee for use in research in accordance with an RDRC-approved protocol or an IND protocol accepted by FDA, the NRC does not believe the Part 35 licensee should be required to reassay the dosage. Licensees should note that if a unit dosage is changed or manipulated in any way it is no longer considered to be a unit dosage and will need to be reassayed before it is administered.

For other than unit doses, paragraph (c) allows the licensee to determine the dosage by direct measurement of radioactivity; by combination of direct measurement of radioactivity and mathematical calculations; or by combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under § 32.72 or an equivalent Agreement State requirement. The current rule limits the licensee to using direct measurement for determining the activity of a photon-emitting radionuclide, but allows alpha-or beta-emitting radionuclides to be measured either by direct measurement or by combination of measurements and calculations. This change allows licensees flexibility in determining dosages and does not distinguish between the type of the radiation (e.g., alpha, beta, or photon) and the way the determination is made.

Paragraph (d) permits a licensee to use a dosage if the dosage does not differ from the prescribed dosage by more than 20 percent or if the dosage falls within the prescribed dosage range. We believe that the rule should allow for some deviation from the prescribed dosage if the licensee chooses to prescribe a dosage rather than a dosage range. Without this allowed deviation, the administered dosage would need to match the prescribed dosage. We have not allowed a deviation outside of the prescribed range because we believe that allowing the AU to establish a dosage range provides the AU with the needed flexibility. The final paragraph (d) codifies requirements that are currently imposed on licensees by license conditions and provides guidance regarding allowed deviations for a dosage range. This does not prevent an AU from revising the prescribed dosage at any time prior to the administration.

The recordkeeping requirements for this section would appear in § 35.2063, Records of dosages of unsealed byproduct material for medical use.

Section 35.65, Authorization for calibration, transmission, and reference sources, is a new section that replaces the current § 35.57. Paragraph (a) was revised to allow the receipt, possession, and use of sealed sources for the purposes of this section if they do not exceed 1.11 GBq (30 mCi) each and they are manufactured and distributed by a person licensed under § 32.74 or equivalent Agreement State regulations. Paragraph (b) was revised to allow the receipt, possession, and use of sealed sources for the purposes of this section if they do not exceed 1.11 GBq (30 mCi) each and they are redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions. In paragraphs (b) and (c) of the final rule, the references in the current § 35.57 to §§ 35.100 and 35.200 were deleted because specific radionuclides were not listed in these sections. Paragraph (c) was revised to allow possession of calibration and reference sources with half-lives not longer than 120 days. The current section only allows possession of sources with half-lives not longer than 100 days. This change has been made so that the section would be consistent with the financial assurance regulations in Part 30. Paragraph (d) was revised to allow possession of any byproduct material with a half-life longer than 120 days in individual amounts that do not exceed the smaller of the following two values: 7.4 Megabecquerels (MBq) (200 μCi) or 1000 times the quantities in Appendix B of Part 30. This change has been made to limit the possession activity below the level where financial assurance is required. In paragraph (e), the possession limit for Tc-99m was deleted. The Commission believes that it is not necessary to limit the possession of Tc-99m for calibration and reference sources because there are no possession limits for Tc-99m associated with the use of Tc-99m under § 35.100 or § 35.200.

Section 35.67, Requirements for possession of sealed sources and brachytherapy sources, is a new section that replaces the current § 35.59. Paragraph (a) continues to require that the licensee follow the radiation safety and handling instructions supplied by the manufacturer, but the requirement to maintain the instructions for the duration of source use has been deleted. Paragraph (b) requires that a source be tested for leakage before its first use, unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months, and the source is tested for leakage at intervals not to exceed 6 months or at other intervals approved in the Sealed Source and Device Registry (SSDR).[1] The SSDR certificates, in most cases, will include a requirement for leak-testing. Approved intervals for testing are based on information regarding source design

[1] A national registry that contains all the registration certificates generated by both NRC and the Agreement States. Registration certificates summarize the radiation safety information submitted by the applicant, and describe the licensing and use conditions approved for the product.

construction that is provided by the manufacturer.

Paragraph (c) retains the detection level for leakage at 185 Becquerels (Bq) (0.005 microcuries (μCi). The NRC deleted the prescriptive requirements on how to satisfy the leak test requirements in the current § 35.59(c) to reflect the more risk-informed, performance-based nature of this final rule. Paragraph (d) requires that leak test records be maintained in accordance with § 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources. We revised paragraph (e) to give the licensee two additional alternatives for action after a leaking source has been identified. The final rule gives the licensee the added flexibility of repairing or disposing of the source in accordance with Parts 20 and 30 if the leakage test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The current rule only allows the licensee to withdraw the sealed source from use and store it in accordance with the requirements in Parts 20 and 30. The licensee is still required to report to the NRC if a leakage test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. Reporting requirements for this section are in § 35.3067, Report of a leaking source.

We amended paragraph (g) to change the frequency for source inventories from quarterly to semi-annually to reduce the regulatory burden on licensees and to exempt gamma stereotactic radiosurgery sources from the requirement for physical inventories. However, the final rule does not preclude the licensee from conducting an inventory on a more frequent basis. The recordkeeping requirements for this section were moved to § 35.2067, Records of leak tests and inventory of sealed sources and brachytherapy sources.

We deleted paragraphs (h) and (i) in the current § 35.59 because radiation surveys are addressed under Part 20.

Section 35.69, Labeling of vials and syringes, is a new section that replaces the current §§ 35.60 and 35.61. It requires that syringes and vials containing unsealed byproduct material be labeled to identify the radioactive drug. It also requires that syringe shields and vial shields be labeled unless the label on the syringe or vial is visible when shielded. These requirements are needed because the Commission does not believe that the labeling requirements in Part 20 are sufficient to ensure that syringes, vials, syringe shields, or vial shields are properly labeled to identify the radioactive drug. In addition, the Commission believes that labeling helps to reduce administration errors.

The NRC does not address shielding of vials and syringes in this section. Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter. We believe that the licensee should have flexibility in complying with these limits.

The NRC revised § 35.70, Surveys of ambient radiation exposure rate, was revised. The term ''contamination'' was deleted from the title because this section no longer addresses contamination surveys. The final rule requires that licensees survey, at the end of each day of use, all areas where unsealed byproduct material requiring written directives were prepared for use or administered, except areas where patients or human research subjects are confined when they cannot be released under § 35.75. Maintaining the requirement for surveys in areas where unsealed byproduct material requiring a written directive is used is consistent with the Commission's direction for a more risk-informed rule.

Licensees are required to show compliance with the public and occupational dose limits specified in Part 20 of this chapter and specifically to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities (§ 20.1101). In situations where radioactive material is used at levels that would not require a survey under this section, the licensee should be aware that a survey may be required by § 20.1501. The Commission believes that licensees will continue to perform radiation surveys as dictated by ''good health physics'' practices.

The recordkeeping requirements for this section are in § 35.2070, Records of surveys for ambient radiation exposure rate. All other requirements in the current § 35.70 were deleted.

The NRC revised § 35.75, Release of individuals containing unsealed byproduct material or implants containing byproduct material. We amended the title of the section and paragraph (a) to delete the term ''permanent.'' This clarifies that this section applies to all individuals released from licensee control. Paragraph (b) was revised to specify that licensees may provide instructions to either the released individual or to the individual's parent or guardian and to replace the term ''dose'' with the term ''total effective dose equivalent.'' The first change acknowledges that, in some cases, it is not appropriate to provide the individual being released with instructions (e.g., the individual is a minor or incapable of understanding the instructions). The later change has been made to clarify what is meant by ''dose'' in this section.

We modified paragraph (b)(2) to state ''potential consequences, if any,'' of failure to follow the guidance. The Commission recognizes that, at low doses, there may be no consequences to continued breast-feeding. A patient may be unnecessarily alarmed if he/she is provided with information on consequences. Therefore, if consequences are not anticipated, the licensee would not be required to provide information to the individual.

We amended the footnote to reference NUREG–1556, Volume 9 (draft), ''Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Licenses,'' that superseded Regulatory Guide 8.39.

We revised paragraphs (c) and (d) to indicate that the recordkeeping requirements for this section are in § 35.2075, Records of the release of individuals containing radioactive drugs or implants containing byproduct material.

The NRC revised § 35.80, Provision of mobile medical service. We changed the title to make it clear that the provisions in this part apply to all mobile medical services and not just to mobile nuclear medicine services. We deleted the current paragraphs (a), (b), and (c) because the use of unsealed byproduct material is limited by the requirements in §§ 35.100 and 35.200, and control and security of material are addressed in Part 20. The remainder of the current requirements were incorporated into paragraphs (a) or (c) of the final rule.

Paragraph (a) requires the mobile medical service provider to obtain a letter from its client that permits the use of byproduct material at the client's address. This letter should clearly delineate the authority and responsibility of the licensee and the client. This paragraph also requires that the mobile medical service provider checks the instruments used to measure the activity of unsealed byproduct materials for constancy before medical use at each address of use or on each day of use, whichever is more frequent. For example, if a mobile medical service licensee provides service to more than one client in a day, the instruments would need to be checked at each client's address. The Commission recognizes that the standard of practice is to check other types of equipment, such as gamma cameras, for proper operation at each place of use. Therefore, the Commission has not included any requirements to check this type of equipment in the final rule.